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A STUDY TO DETERMINE THE OPTIMAL FEASIBLE
MODEL FOR THE QUALITY ASSURANCE/RISK
MANAGEMENT PROGRAM AT NAVAL HOSPITAL,
BETHESDA

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SUBMITTED TO THE FACULTY OF BAYLOR UNIVERSITY
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FOR THE DEGREE OF MASTER OF HEALTH ADMINISTRATION

PEGGY J. BREAUX
LIEUTENANT, NC, USN

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I. INTRODUCTION

Development of the Problem

Health care professionals in the Navy Medical Department are continuously concerned with improving the quality of health care provided to its beneficiaries. To determine whether quality health care is actually provided to the consumer, the care is reviewed and evaluated through various mechanisms. The methodology most frequently used in the past was the "Performance Evaluation Procedure for Auditing and Improving Patient Care" (PEP).¹ This was developed by the Joint Commission on Accreditation of Hospitals (JCAH) as a retrospective medical care audit. Additionally, related quality assessment review functions, e.g. pharmacy and therapeutics, infection control, blood utilization, delineation of clinical privileges, and nursing care audits were conducted evaluating patient care and clinical performance. These functions however, were not coordinated with the medical care audit activities. JCAH recognized the medical care evaluation programs met with limited success. It was recognized that improvement in patient care and clinic performance was not adequate nor apparent to the extent anticipated. In lieu of the diverse medical care evaluation programs at the local level, a more systematic approach was needed to coordinate and evaluate quality health care as well as meet the new JCAH quality assurance standards.

The new quality assurance standards developed by JCAH are intended to assist medical treatment facilities in implementing an over all quality assurance/risk management program designed to assure delivery of optimal patient care. This requires medical facilities to coordinate and integrate, to the degree possible, all quality assurance/risk management programs.

The Naval Medical Command (formerly Bureau of Medicine & Surgery) (BUMED), recognized the need to provide central coordination and direction to all naval medical facilities in establishing quality assurance/risk management programs. To accomplish this goal, the Quality Assurance/Risk Management Manual (BUMEDINST 6320.62) set forth guidelines for program development. This instruction provides specific guidelines but still allows considerable flexibility in implementing and administering the program.

Naval Hospital, Bethesda, therefore, developed a Quality Assurance/Risk Management Plan according to the guidelines of BUMEDINST 6320.62 and the JCAH Accreditation Manual for Hospitals 1981 Edition. However, during a JCAH accreditation survey on November 12, 13, & 16, 1981, many discrepancies in the plan and documentation of the hospitals' quality assurance/risk management program were found resulting in serious doubts regarding the future accreditation of Naval Hospital, Bethesda.² The Accreditation Committee of the Board of Commissioners decided to continue the accreditation status of the hospital contingent upon the findings of a Follow-up Physician Visit within sixty days of the decision.³ Additionally, a BUMED-27 team review on November 4 & 8, 1982, consistently found two critical elements, "integration of problem-focused reviews by departments and committees, and top level coordination of all quality assurance efforts", missing from the program.⁴

Changes were made in the quality assurance/risk management plan and program prior to the Follow-up Physician Visit. This visit on June 29, 1982 resulted in a continued accreditation with a full JCAH Survey scheduled for the fourth quarter of 1982.⁵ By the time of the JCAH Survey on November 16, 17, & 18, 1982, Naval Hospital, Bethesda had made tremendous progress in the area of quality assurance documentation⁶ resulting in a three-year accreditation.⁷

The changes which were made in the quality assurance/risk management program were done to result in more efficient tracking and accountability of the quality assurance/risk management program. However, the end result, which is now apparent, is a horrendous paper exercise which is done manually. In the last six months, there have been three incidents in Radiology resulting in malpractice claims and three falls involving civilian employees with lost work days which were not picked up or acted upon in a timely manner within the quality assurance/risk management activities.⁸ The centralization of the quality assurance/risk management program and the tendency for all problems to flow to the top for resolution was further complicated by the restructuring/reorganization of the Naval Hospital which occurred in 1982.

The reorganization of BUMED in September, 1982 resulted in a more decentralized organizational structure in Naval Hospital, Bethesda. Originally all areas of the hospital fell either under the Director of Clinical Services (DCS) or the Director of Administrative Service (DAS). With the restructuring, the areas were divided in five directorates reporting through the Executive Office (XO) to the Commanding Officer (CO). Organizational charts reflecting these different structures may be found in appendix A. The new structure has resulted in an increased number of personnel in the chain-of-command. This is an important factor contributing to the difficulty in the quality assurance/risk management program although not causative in nature.

The QA/RM Program was obviously not meeting its mission in view of the centralization, problem flow to the top and the new organization directed. Therefore, the problem is to determine the optimal feasible model for the Quality Assurance/Risk Management Program at Naval Hospital, Bethesda.

Problem Analysis

Statement of the Problem

The problem is to determine the optimal feasible model for the quality assurance/risk management (QA/RM) program at Naval Hospital, Bethesda.

Objectives

This study is meant to be a comprehensive study of the current Naval Hospital, Bethesda Quality Assurance/Risk Management Program. Therefore, the objectives of this study are to:

1. Conduct a comprehensive review of the literature to increase the researcher's fund of knowledge and to provide a foundation for conducting the study.
2. Analyze Naval Hospital, Bethesda's current Quality Assurance/Risk Management Program.
3. Determine alternate models for a Quality Assurance/Risk Management Program.
4. Compare the existing program with the alternative models based on pre-established criteria to determine the program's efficiency.
5. Effectuate recommendations for implementation of an improved quality assurance/risk management model at Naval Hospital, Bethesda, and possibly, Navy wide.

Criteria

The criteria for this study shall be:

1. The QA/RM program shall meet the standards set forth by JCAH in their Accreditation Manual for Hospitals.
2. The QA/RM program shall meet the requirements set forth in BUMED Instruction 6320.62 by Naval Medical Command.

3. There shall be 100% compliance by all departments/divisions within Naval Hospital, Bethesda in maintaining the tracking system for QA/RM problems.
4. The QA/RM program shall result in less than 2% of the QA/RM problems forwarded to the QA/RM Committee being deemed by the Committee as having solvable at the department or directorate level.

Assumptions

For the purposes of this study, the following assumptions shall be made:

1. Although the Naval Medical Command is currently revising the BUMED INSTRUCTION 6320.62, it shall result in no significant changes in requirements for the QA/RM program.
2. Other Naval facilities are experiencing similar difficulties and the information resulting from this study shall be of value to other Navy hospitals.

Limitations

This study shall be limited by the following factors:

1. To fully develop a model for a hospital QA/RM Program Navy wide would require an indepth analysis of data for all Navy hospitals, an effort which is beyond the scope of a Master's level research project. Additionally, the guidelines for the Navy QA/RM Program are currently being revised by Naval Medical Command.
2. The model developed must follow the new organizational structure of Naval Hospital, Bethesda.
3. The model developed shall require no additional manpower or budget.

Despite these limitations, it is believed a meaningful study can be conducted and, as a result, viable recommendations made.

Definitions

For the purpose of this study, it is pertinent to define the following terms:

Quality Assurance is "the measurement of the level of care provided (assessment) and, when necessary, mechanisms to improve it."⁹

Quality Assessment is "the evaluation based upon what happens in the course of treatment; it considers the professional management of patients."¹⁰

Risk Management is "the results-oriented approach to protecting the assets of a business so that its operations can grow profitably."¹¹

Research Methodology

The objectives of this study were carried out in a four-phase methodology. Phase One, the Preliminary Phase, involved an extensive literature review. This was done partially in preparation of this graduate research project; however, due to the voluminous amount of literature available on the subject, the literature review entailed an ongoing process throughout the research effort.

Phase Two, the Evaluation Phase, comprised a comprehensive appraisal of the current QA/RM program at Naval Hospital, Bethesda. Of prime consideration was the flow of information and tracking of QA problems through the system. This was accomplished by becoming thoroughly familiar with the QA/RM instruction for the hospital, interviewing the QA/RM personnel at all levels within the hospital, and tracking QA/RM problems via reports, minutes of meetings, etc., through the complete QA/RM system to determine the actual flow of information and paper. Models such as flow charts and procedural flow charts were utilized to display the information gained. Additionally, the information was compared to the predetermined criteria. Criteria 1 and 2 were evaluated by

comparing the program against the requirements in the JCAH manual and BUMEDINST 6320.62. Criterion 3 was evaluated by sampling the departments/divisions within the hospital and on the basic of documented records determining compliance with the tracking system so that no problem was lost. Criterion 4 was measured by looking at the QA/RM Committee minutes and checking for determination by the committee that the problem should have been handled at a lower level or immediate referral of the problem back to the originating department/division.

Phase Three, the Procedural Analysis Phase, developed the proposed optimal feasible model for the QA/RM program at Naval Hospital, Bethesda. The positive and negative aspects of the existing system were analyzed and the proposed model was then designed and analyzed according to the criteria.

Phase Four, the Recommendation Phase, consisted of specific recommendations based on the preceding phases being promulgated.

1 Charles M. Jacobs, and Nancy D. Jacobs, The PEP Primer: The JCAH Performance Evaluation Procedure for Auditing and Improving Patient Care, (Illinois: JCAH, 1974), p.5.

2 "A Navy Problem", The Washington Post, 7 April 1982, Sec. 4, p. Cl.

3 JCAH Letter of 7 May 1982.

4

5 BUMED Letter of 15 June 1982.

6

7 Naval Hospital, Bethesda (Maryland). Minutes of the JCAH Summation Conference, 18 November 1982. (Typewritten)

8

Interview with CDR Jeffrey W. Baldwin, MSC, USN, Director of Hospital Administration, Naval Hospital, Naval Medical Command, National Capital Region, Bethesda, Maryland, 9 August 1983.

9 N.O. Graham, ed., Quality Assurance in Hospitals, (Maryland: Aspen Systems Corporation, 1982).p.306.
10

Ibid.
11

W.R. Fifer, "Risk Management and Medical Malpractice: An Overview of the Issues," Quality Review Bulletin (April 1979), p.12

II. LITERATURE REVIEW

Within the last ten years, a tremendous amount of literature has been written on the area of quality assurance. However, for the purpose of this paper only the specific areas of trends and factors leading to the development of quality assurance, legislative and organization influence on quality assurance, quality of care, quality assurance in health care, evaluation, organization, structure, control, and studies within the military health care system will be discussed.

Trends and Factors Leading to the Development of Quality Assurance.

Within the last half of this century and especially since the advent of Medicare and Medicaid, a number of forces and trends have been discernible. Consumerism, a movement which has as its mission to increase the rights and powers of the purchasers of a service or product, in their relationships with the providers or sellers, has become a permanent part of the United States culture. The consumer movement has been directed toward accountability, equalization of bargaining power and establishment of regulations. The concept of "buyer-beware" philosophy has been eroding for those services and products related to performance and quality.¹

In the health field, the problems have been related to accessibility, quality, quantity, and cost of health services. For example, in 1976 in the area of cost, health care spending reached \$139.3 billion, representing more than 8.6 percent of the U.S. gross national product.² However, the inequitable distribution of health resources and health care among different

social and economic classes and geographic areas has become a major concern. The care delivered to minority or low income groups in rural or urban areas has been characterized as fragmented. In addition, the failure to provide citizens the latest developments in scientific & technological health care has led to increasing dissatisfaction with the present health care delivery system. However, the majority of today's health care consumers have gained a higher life expectancy than non-consumers, are better educated and have a higher income base. Yet, they are confronted with the problems of mounting inflation and expect health care at reasonable costs. This combination of forces has given rise to consumer movements, spiraling costs of diagnostic equipment and services, the rising consciousness of minority groups, failure of equipment, lack of accessibility, maldistribution of providers, and impersonality in health care institutions.³

One special group of consumers, the third-party payers (insurance carriers, unions and government) have played a growing role and are a force in the quality assurance movement. They have been especially concerned about costs, allegations of excessive utilization of services and ineffective care. The prospect of a national health insurance has caused additional concern in regard to the quality of services rendered. Health professionals can no longer render services that are accepted unquestionably. This questioning attitude, markedly noted on the part of the third-party payer, has permeated the complex negotiations that are giving rise to a national health policy and is influencing legislation.

The emphasis of the social accountability of professionals, now extended to the institution or to groups representing the profession, is a new and major force. Some health professionals frequently overlook the fact that they operate

under a social mandate.⁴ This mandate implies that services are performed for persons, and the services are recognized as legitimate. Concomitant with the giving of this might is the expectation that quality of service and the effects they produce are accountable. With the increase in knowledge by the public about professional practice, an insistent demand for quality became more apparent. Health institutions are now being asked to account for quality of services given by practitioners to their patients and clients. Furthermore, there is a growing attitude among the public to self evaluation, whether it is done by the direct provider or by the patient, is not enough. Evaluation must be supported by a system of surveillance and correction, a system that results in reports that can be shared with the public.

Legislative and Organization Influence on Quality Assurance

Current health legislations which include a mandate for quality assurance had its origins in the 1960's when concern increased for equal health care for all. Health care for every U.S. citizens is a right, not a privilege. This was the overriding phase. Congress passed Public Law 89-749 in 1966 specifically stating this right: "The fulfillment of our national purpose depends upon promoting and assuring the highest level of health attainable, for every person, in an environment which contributes positively to healthful individual and family living".⁵ This established the necessity for a financing mechanism enabling all citizens to purchase health care. In response, bills have currently been drafted to offer a more comprehensive payment plan. The intent of these bills is to insure that low-income, disabled and the elderly have a right and financial access to health care.

McClure⁶ pointed out that the health care system has two incompatible roads; namely, either the increased governmental regulation or management of the health care system, or initiating basic structural reforms to make the system more self regulating in interest via traditional mechanism of the market and consumer choice.

To prevent government control several self-regulating programs have been proposed and implemented. One proposal was a national health insurance introduced in the 93rd Congress. The proposal was designed to establish a program of comprehensive health care benefits for all citizens of the nation through a reorganized, coordinated and financed health care delivery system. This system aimed to bring together community health resources and maximize the potential for local and state determination of meeting health care needs. This House of Representatives Bill (H.R.I) proposed to establish a national focus for health programs, consolidating federal health programs administered by the Department of Health, Education, and Welfare in a new Department of Health headed by a Secretary of Health at the cabinet level. When passed by Congress in 1972, it created the Professional Standard Review Organization (PSRO). The official title is Section 249 F of Public Law 92-603, the Social Security Amendments of 1972.^{7,8} The general provision of this law clearly states:⁹

Sec. 1151. In order to promote the effective, efficient and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this Act and in recognition of the interests of patients, the public, practitioners, and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under the Social Security Act will conform to appropriate professional standards for the provision of health care and that payment for such services will be made-

- 1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

- 2) in the care of services provided by a hospital or other health care facility on an inpatient basis, only when and for such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.

As a quality assurance system, the scope of PSRO is limited in two important ways. Only the care delivered to persons enrolled in a federally financed program will be reviewed, and only service rendered in a hospital setting and the nursing homes providing medical care are subject to review. Although the present law is focused primarily on hospital care, it is apparent that eventual review of quality care in the ambulatory setting will receive increased attention in the next few years.

Since the original law specified that only physicians would be directly involved in PSRO, other health professionals including dietitians, nutritionists, nurses, midwives and other allied health professionals are confronted with the challenge of improving their professional services through the review system. Recently, Dr. Jonathan Fielding, Acting Director of the Division of Peer Review¹⁰ indicated that the PSRO is required to provide evidence over time that "non-physician" health care practitioners have become involved in the development and on-going modifications of norms, criteria, and standards for their areas of practice. The other avenue of involvement of non-physician health care providers to the PSRO is through direct service to the advisory group that has been established in each state or district council.

The Health System Agency (HSA) involved with the PSRO is a health planning group dedicated to the achievement of equal access to quality health care at reasonable costs to all health care consumers. Established under P.L. 93-641, the National Health Planning and Resources Development Act of 1974, its primary responsibility is health planning and resources development.¹¹ It is responsible

for data collection, development of health systems plan with a detailed statement of goals, issuance of grants and contracts to assist agencies in planning and program development. In addition, it coordinates its activities with its counterparts PSRO and other regional health planning and administrative agencies. The HSA government body was designed for broad consumer and provider representation, with consumers representing the majority. Equitable distribution of quality health care which the consumer can afford is another responsibility of over two hundred HSAs in the United States.

Another legislative body involved in quality assurance programs is the Experimental Medical Review Organization (EMCRO). Its purpose is to develop working models with which to test the feasibility of conducting systematic and on-going review of medical care under auspices acceptable to the several medical professional communities, to the public, to the government and to the third-party payers.¹²

Health Maintenance Organization (HMO) legislation has also influenced the need for developing methods for assessing quality health care. This legislation requires an on-going quality assurance program which stresses both health services and outcomes, and assures that health services provided meet quality standards.¹³

The American Hospital Association (AHA) recently implemented a quality assurance program to improve the quality of patient care in the hospital. Surveillance was a necessary but limited part of the total program that was designed to bring about change primarily through continuing education. The AHA feels that the provision of medical services is the primary responsibility of the hospital and that the responsibility for such belongs to the hospitals, but that authority and accountability for the conduct of the program are delegated

to the medical staff.^{14,15}

The Joint Commission on Accreditation of Hospitals (JCAH), in its regulatory role assigned and supported by health professionals and hospital organizations, was concerned with the assurance of quality patient care in hospitals. Porterfield¹⁶ states that JCAH is now more pointedly concerned with explicit quality assurance measured for the medical care in hospitals. The JCAH required that a system of quality assurance be initiated and documented no later than 1973 and be carried to complete implementation without delay. The JCAH goal was to make it possible for every accredited hospital to demonstrate its right to exemption from review by its Regional Professional Standard Review Organization by virtue of its own effective system before January 1, 1976.¹⁷

Implementation of the laws and health organization activities for quality assurance in health care are likely to continue at a rapid pace during the next decade. The goal of assuring the highest level of health attainable for every person is not easily achieved, however, the profession is obligated to fulfill its responsibilities without reservations.

Quality-of-Care

With these foregoing activities in mind, it appears appropriate to examine the concept of quality-of-care. Quality is a term with various definitions, and there is some risk that it will become a slogan before it becomes a valid indicator of health care. Approached from several vantage points, quality-of-care can be expressed in two particulars.^{18,19,20} The first is a concept that defines quality from a health provider-patient interaction viewpoint, and the second is to define quality of the health care system as a

whole.

Explaining further the two concepts as elaborated by Brook & Avery²¹, health provider-patient interaction includes the following quality care variables : 1) adequacy of the "art-of-care", 2) adequacy of the technical management of the symptoms or signs which the patient presents to the provider, and 3) the adequacy of the efficiency of care. Art-of-care refers to the manner the health care provider relates to the patient as an individual as measured by its sensitivity, openness and non-authoritarian nature. Technical care is taken to represent the adequacy of the performance of preventive, diagnostic and therapeutic procedures for the patient. Efficiency refers to the ability of the provider to arrive at an favorable solution to the patients' problem while consuming the minimum amount of resources.

In formulating the definition of quality-of-care as a whole, two additional areas are implicitly considered: 1) accessibility of the service and 2) availability of the service. A broader scope would include health professionals other than physicians and extend throughout an entire episode of illness as opposed to an isolated visit. The input of nurses, dietitians, nutritionists, therapists or pharmacists who make independent decisions should be considered in a statement about the quality of health care systems as a whole.

Clearly, quality then is a multidimensional concept involving an overlapping and often unspecified value and measurement system that ranges from outcomes of care (e.g., days in bed, number of dietary consultations) to quality during the process of dying (reflected in phrases like "death with dignity"). In most instances the concepts are compounded by the biases of the evaluators. However, in order to define quality in the analytical sense,

objective measures are needed. Unfortunately, aspects of quality-of-care are not well established in all aspects of the medical program. This is perhaps due to the complex interaction between process and outcome which makes it easier to define no quality or poor quality rather than to assess good quality. The judgement of quality derives, in the main, from the standard of management acceptable to the leaders of the profession at any given time.²² Those standards apply to particular situations and must, therefore, reflect current knowledge and orientations, and are subject to change as knowledge advances and the scope of the provider responsibility is redefined.

Quality Assurance in Health Care

Among the earliest efforts to assess adequacy of medical and nursing care and its impact on the recipients is the work of Florence Nightingale.²³ By comparing mortality experience in the British Armed Forces during the Crimean War among civilian populations, Nightingale in her notes on Matters Affecting the Health, Efficiency, and Hospital Administration of the British Army, published in 1858, brought forcefully to the attention of the government and the public the lack of standards of care. Although, by today's standards, the data were crude, the report was nevertheless instrumental in bringing about basic reforms in the living standards and health services of the British Armed Forces. In 1908, Groves²⁴ issued a plea for the uniform registration of the results of surgical operations. The basis for his plea was succinctly stated:²⁵

If a surgeon makes a speciality of some disease or operation and tabulates all his own results, or another by chance has some notable successes and records them, or the author of a textbook collects published records of various writers and summarizes them, is it not obvious that such collection of figures will represent the best and not the average results?

In order to obtain information about "average results," Groves conducted a survey of the fifty hospitals in Great Britain with over two hundred beds. Data from twenty-seven hospitals showed a 44% operative mortality from radical operations for malignant diseases, 24% mortality from prostatectomy, and a 9% mortality from appendectomy. The result of his survey raised two important points: 1) the need to develop an acceptable standard classification for diseases and operations that would permit comparisons of data from different hospitals, and 2) the need to establish a follow-up system for particular categories of diseases, that would allow assessment of long-term results.

In 1914, Codeman, a surgeon at the Massachusetts General Hospital, lamented the lack of outcome assessment in the United States.²⁶

One might say that the instruction of the students is irrespective of the results to the patients, but let us suppose, in surgery, for example, that all the operations which have been watched by these students have been misdirected efforts at the cure of the disease, and the students have learned to do something which is not worthwhile and does not really improve the patient. The product of the hospital in this case, even as regards student instruction, would be nil—even worse than nil. We are therefore, referred again to the classification of disease and the results to the patients, because a student would naturally wish to receive his instruction at a hospital where the treatment was shown to be of benefit to the patients. We may then say that the product in the number of cases treated, depends on whether or not the cases are well treated.

In an effort to determine whether patients were well treated, Codeman attempted to institute a follow-up system at the Massachusetts General Hospital. Not being successful, he instituted a follow-up system in his own hospital. From his study. Codeman was able to determine whether diagnosis was correct, the operation was a technical success, or the patients had benefited from the operation through an intensive follow-up system be designed.

After considering the significant contributions that Nightingale, Groves, and Codeman made to the field of quality assurance, little substantive work was

done during the next three decades. However, by the turn of the 20th century, Flexner reported a study of the poor state of medical education in the nations institutions.²⁷ His report prompted major improvements in the structure and content of medical education in the United States. By 1913, the American College of Surgeons was established and became the accrediting organization that generated standards for physician's education and performance.

When interest in assessing the quality-of-care began again in the late forties and fifties, the focus of these efforts had undergone a striking metamorphosis. No longer was the assessment of quality-of-care based on end-results of care. Instead emphasis was placed on examining the adequacy of diagnostic investigations and therapeutic interventions which involved the process of medical care.

Three landmark studies of this period were: the study of the quality of ambulatory care provided in the Health Insurance Plan of New York City by Morehead;²⁸ the study of the quality-of-care rendered in a select group of short-term general hospitals in Michigan by Payne²⁹; and the study by Peterson³⁰ on the quality-of-care delivered by general practitioners in North Carolina.

Morehead reported that assessment relied on physicians' judgements of the process of care, arrived at both by reviewing medical records and talking to the physicians who gave care. Payne judged adequacy of the process of care by comparing the information contained in the medical records against a set of explicit, disease-specific criteria established by a group of physicians. Peterson observed the general practitioners while they were providing care, scored their practice on the basis of adequacy of the history, physical examinations, therapy, and type and amount of follow-up care.

Other attempts to assess quality-of-care during the period of the 1930's and 1940's focused on structural variables, such as innate characteristics of physicians (e.g., age, length of training), facilities, staffing patterns and organizational structures. The best known proponent of this type of assessment was the Joint Commission on the Accreditation of Hospitals (JCAH), which sent experts to hospitals to evaluate quality-of-care against a check list of minimum standards. The first scientific method for this type of assessment was described by Lembocke in a series of self-developed criteria for expected physician performance.³¹

Perhaps the most significant contribution to the identification of the current state-of-the-art in quality assurance in health care is described in a monograph of a Conference on Quality Assurance of Medical Care held in January, 1973.³² The purpose of the conference was to bring together a large number of experts, knowledgeable in quality care, who would present their views and findings upon conclusion of the conference. Pellegrino closed the conference with the following statements:³³

The amount of effort dedicated to quality assurance, as well as the extent and variety of approaches, is impressive. One can detect the beginning impingement of social needs upon the health care apparatus. But, the overall impression is that the effort is still piecemeal and without direction. There is clear absence of a rational, consciously developed plan applicable to the entire nation. There is no clear focus on the social purposes to which the whole process of quality assurance should be dedicated and from which a larger design can be deduced.

Therefore, in spite of the many efforts, the state-of-the-art in quality assurance still lacked a systematic plan.

Brook has written an extensive and comprehensive review of medical care evaluation literature.^{34,35,36} He pointed out major classic studies in the medical care evaluative field emphasizing the methods rather than results obtained.

His conclusion was that reported major studies measured the process of medical care and not the outcome of medical care. However, process and outcome measures should ideally be used in combination. Few studies measured the whole of the traditional medical care process; rather, the emphasis was placed on a single component of the process. He further concluded that when outcome was measured, usually one of two parameters were assessed, such as mortality or unnecessary operations. Very few studies attempted to relate the process of medical care to the outcome of medical care. The chief reason for this contradiction probably lies in the difficulty to define health, which is required if outcomes form the frame of reference for the study of quality-of-care. Health is an ambiguous concept that can be narrowly or broadly defined to embrace fewer or more numerous areas of human performance and welfare.^{37, 38} Siegel maintains that it is theoretically impossible to define health.

This review supports several conclusions about the state-of-art of quality evaluation which are directly relevant to a description of present day attempts to regulate the quality of medical care. It is apparent that new conceptual frameworks have not developed in the last two decades. Although three time honored approaches stand out - evaluation of quality using structure, process, and outcome criteria - there is no consensus as to which produces the most valid judgements of quality-of-care. In each approach, judgements of quality have been based on either implicit or explicit criteria. Here again, no consensus exists regarding which type of judgements provide the most valid result.

Evaluation Studies on Quality Assurance

Evaluation is an essential element in a quality assurance program. Greater

awareness of the importance of the systematic and scientific approach to the determination of the success or failure of social institutions and their program of activities is increasing the need for evaluation by many disciplines. One result is a growing volume of literature dealing with the subject of evaluation and quality assurance.

Evaluation can be defined as the process of collecting data to acquire information for decision making.³⁹ Evaluation can focus on a worker's job performance, a new procedure or a new technique. The purpose of quality evaluation is to point out those areas of acceptable performance and give credit to those involved in contributing to quality, and to locate those areas of unacceptable performance where improvement can be accomplished. What is common in the process of evaluation is the notion of judging merit. The evaluator is examining the weighing of a phenomenon against some explicit yardstick.^{40,41}

Several studies have been done on the subject of health care evaluations. Each has provided valuable information on the overall use of evaluation, guidelines for conduct, and examples of applications. Schulberg, Sheldon, and Baker have produced an excellent collection of specific studies on program evaluation in the health fields, which include contributions on general conceptual and methodological issues, as well as precise techniques of design and measurement, application of findings, and experiences and problems in implementing research findings.⁴²

Weiss⁴³ defended the field of evaluation and cautioned that evaluations are not the drones of the research fraternity, methods and techniques drudging away on dull issues and compromising their integrity out in the corrupt world. Rather, an evaluator is a highly skilled researcher who can make research work

when it is dealing with the complexities of real people in real programs run by real organizations.

In a conference sponsored by the American Institute of Research in 1970 a forum was provided to discuss means of solving problems encountered in using known techniques of evaluation. Differences between ideal and actual practice were clearly recognized as a problem. The conference ended with a recommendation that the process of evaluation be improved in order that programs of social change may have the proper leverage to move forward.⁴⁴

The field of education has also demonstrated concern over the lack of a unified approach to evaluation, as expressed in a yearbook published by the National Society for the Study of Education.⁴⁵ Contributors pointed out that evaluation has not kept pace with new concepts of educational practice. Too frequently evaluators are measurement experts segregated from the changing social and educational environment in which learning and teaching are conducted.⁴⁶ In the same publication, Stake and Denny concluded that there is no one right way, no one value, no one truth.⁴⁷ Further, education evaluators have done little thus far in devising procedures for establishing meaningful and useful standards. Successful evaluation depends on recognition of many purposes, many outcomes, and many values and it depends upon a methodology that portrays these complexities throughout the educational process.

There is an agreement by most authors of evaluation literature that evaluation should be a continuous process in every social action program because its findings can serve to modify goals and provide insight to redesign certain aspects of the program. There is also agreement that the task of determining the effectiveness of an entire program is extremely difficult. As the program becomes more complex, so do the problems of evaluations as Suchman pointed

out.⁴⁸

It is not so much the principles of research that make evaluation so difficult, but rather the practical problems of adhering to these principles in the face of administrative considerations.

Theories of Organization

In reviewing the literature only slight differences were found in the way various theorists view organizations conceptually. Stogdill defines the organization as a structured system of behavior with the position and roles accompanying it have the potential of being prestructured.⁴⁹ Barnard views the organization as a system of consciously coordinated personal activities or forces, a system of interrelated activities.⁵⁰ Thompson depicts an organization as a highly rationalized impersonal integration of a large number of specialists operating to achieve some objective, upon which is superimposed a highly elaborate structure of authority.⁵¹ Davis describes an organization as groups of people working together to accomplish an objective.⁵²

Henry Tosi explains five generic characteristics of organization he has found in his research of organization theory. These are discussed below:⁵³

1. Large size is an implicit characteristic. In general, organizations treated in theory are of such a size that within them it is extremely difficult, if not impossible, to maintain close interpersonal relationships with a large number of the members, relative to the total membership.
2. Formalization derives partially from the large size of the organization and the need for some kind of control structure. Formalization simply means that procedures and policies are written and stated in such a way that they become stable, quasi-permanent directions, ranging from very general to very specific, for interaction and decisions. It provides a degree of stability to interaction patterns, regardless of the incumbent of the position in the organization.

3. Rationality is another attribute sought by large organizations. The purpose of imposing a structure is to bring order to a system of activities intended to achieve a goal. The system should be ordered on the basis of "logic and science." The activities of the members should be directed toward the goal. If activities are goal-directed, then resources can be more effectively utilized. Rationality is partially achieved by "goal factoring." The organization has a general goal. This goal is factored, or broken down into subgoals. These are assigned to lower-level units. If these units achieve their purpose or goal, the general organization goal will be attained. Individuals in lower-level units essentially "assume" the goal of the unit when they accept a position. In addition to the obligation, an incumbent will have certain prerogatives to allocate organization resources to accomplish these subunit goals. These prerogatives are often called "authority".

4. Hierarchical structure is therefore related to the nature of the factored goals. Hierarchy is the existence of different degrees of authority at various levels of the organization. It is the chain of formal authority relationships from the top of the structure to its bottom, tying different levels of the organization together. The degree of authority at a particular level may be defined in terms of the range of discretion an individual has over resource allocation, both physical and human. In general, individuals in higher positions tend to have greater discretion and are accorded more status and deference than those at lower levels. It is through the authority structure that the various activities of the organization are tied together in order to achieve some degree of coordination in attaining goals.

5. Specialization is another dimension of the complex organization. Specialization refers to the particular grouping or configuration of activities performed by an individual. The range of activities assigned to a particular position, or individual, should be "rationally" grouped in such a way as to make sense in terms of effectiveness and efficiency. Specialization may be one two types. First it may refer to the division of labor. The particular task is analyzed and broken down into subtasks, which are its primary components. An individual then is assigned to perform these subtasks, which are essentially simpler and more repetitive than the total task requirements required to achieve a result. The individual is able to learn the tasks quickly and also its concomitant skills.

Drawing on organization theory, a hospital is an organization, therefore requiring leadership and management to exist. Peter F. Drucker asserts that an organization exists for a specific purpose and mission, a specific social function.⁵⁴ Thus the organization known as a hospital is no different and based

on the value system of our society, the social contract, has a great social responsibility. Additionally, Kerr White explains the social contract that exists between health care and society. The present system will not be allowed in the provision of health care if it does not meet the perceived needs of society.⁵⁵

One of the foremost concerns with the health care organizations today is fulfilling the social demand and social responsibility to provide delivery of quality health care. The milieu surrounding hospitals is quality assurance and meeting this need within the organization.

Structure

Drucker feels structure is a means to attain the objectives of an institution. Therefore, logically one must start with objectives and strategy to finish with a structure, i.e. structure follows strategy. An effective structure makes possible achievement of objectives and purpose of an organization.⁵⁶

Structure may be defined as the establishment of a pattern of relationships among the components or parts of an organization. Structure is prescriptive and the result of explicit decision making. It serves as the blueprint of the relationships of activities, represented by a printed chart, and set forth in organization manuals, position descriptions, and other formalized documents. It functions as the general framework, delineating certain prescribed function and responsibilities among them.⁵⁷

Koontz, O'Donnell, and Weichrich define an organization structure as a functional element consisting of either a person or group of persons, such as a department or branch that has been designated to meet and accomplish organizational goals and objectives.⁵⁸ This definition will be used in this research project, i.e., a person performing the organizational duties of QA/RM is a QA/RM Coordinator. The QA/RM office is a group of persons under one office performing the duties.

Control

Over twenty-five years ago Lembcke stressed that the purpose of QA systems is to insure that the full benefits of medical knowledge are applied effectively to meet patient needs.⁵⁹ Since Lembcke's seminal work on QA, the other major components of QA systems, criteria setting and measurement of performance, have undergone extensive research and testing. Extant today are numerous methodologies of sufficient reliability and validity to measure and detect large variations in quality of care. Several studies of the effectiveness of QA systems, most notably the 1976 study by the Institute of Medicine, have found that their major failing is not in the quality assessment components of QA systems but in the quality assurance components, i.e., closing the education feedback loop so that assessment results are applied to improve physician's behavior in ordering services.^{60,61,62}

1979, Michael Goran, a former director of the Professional Standards Review Organization (PSRO) program responsible for overseeing the quality and efficiency of hospital care, commented:

The evaluation that has taken place in PSRO hospital review improves the local PSRO's ability to detect problems in the quality and utilization of hospital services. Nowhere near the same progress has been made in correcting problems once they are detected.⁶³

To determine the reasons for this failure to close the educational feedback loop one must examine and contrast three methods of control intended to apply the results of assessment to quality assurance.

Laissez-Faire Self-Control

The first method, the one most commonly used in QA systems is laissez-faire self-control. Most QA systems, recognizing the medical profession's claims to autonomy and self-control, have delegated to physicians the function of providing feedback of quality assessment results. The method typically advocated is one requiring the provision of continuing medical education. This method, often associated with medical audit, is characterized by retrospective feedback (i.e., after a patient's hospital discharge) of assessment results coupled with an educational program designed to remedy deficiencies in medical knowledge detected by the assessment. Despite a few notable successes, the bulk of studies evaluating the effectiveness of continuing medical education have found little or no improvement in quality.^{64,65,66} A number of reasons can be posited for this lack of effectiveness:

1. the educational efforts - whether informal discussions with members of the medical staff or formal lectures on the assessment topic - is frequently not sufficiently relevant to the assessment topic and detected deficiencies in treatment;
2. participation in the educational effort is usually voluntary, leaving the possibility that those who could most benefit do not;
3. the retrospective nature of the feedback is temporally divorced from the actual treatment of patients;
4. the deficiencies in treatment result less from inadequate knowledge than from inadequate application of knowledge.

Regulatory Control

When laissez-faire self-control has failed, achieving control is sometimes attempted through regulation by agencies external to physicians and hospitals. Regulatory controls can be characterized by the imposition of rules, regulation and sanctions that serve to define acceptable medical practice and limit the discretion of individual practitioners. Examples of such controls include the Medicare requirement for certification and recertification of a patients need for hospitalization, the requirement of a patients need for hospitalization, the requirement of many Medicaid programs for pre-authorization of admissions, health care insurer's retroactive claims denials, and the use of the legal system to enforce physician and hospital liability in the rendering of quality care.

As with continuing medical education, there are a few studies documenting the effectiveness of this approach.^{67,68} The majority, however, are inconclusive or show no improvement in physician's performance in ordering necessary and only necessary services.^{69,70,71,72,73,74} Critics of regulatory controls argue that they engender hostility and resistance from physicians and often result in denying patients access to necessary services-in large part because physicians feel harassed by the "bureaucracy" involved in certifying the necessity of such services. Other critics maintain that much of the improvement ostensibly caused by regulatory control is merely "paper compliance" resulting from improved documentation in medical records. Moreover, resorting to the courts to enforce quality compliance may have the untoward consequence of increasing provision of unnecessary services because physicians feel they must practice "defensive medicine."

As discussed, regulatory controls do have a constructive role to play in the design of effective QA systems. This role, however, is limited to situations in which cause-effect (i.e., therapeutic process-outcome) relations are relatively certain and subordinate to control by "mutual adjustment."

Control by Mutual Adjustment

The third method of control, mutual adjustment, is characterized by providing systematic feedback governed by professional discretion in the use of its informational content. Control by mutual adjustment is similar to the laissez-faire self-control in that it employs feedback of assessment results to activate self-control. It differs from laissez-faire self-control, however, in that the feedback is systematically provided, typically on a concurrent basis. The feedback is provided to a particular physician about a particular patient at the time the physician is treating the patient in the hospital. Thus, the feedback is relevant to that particular situation and is temporally associated with the therapeutic decision-making process for the situation.

Compared with regulatory control, control by mutual adjustment shares the characteristics of providing information that intrudes on the physician's decision-making process. However, with regulatory control the information is in the form of rules and regulations prescribing the appropriate manner for ordering (or not ordering) services. With control by mutual adjustment, the feedback is not necessarily prescriptive; rather it is timely information about the patients progress toward the expectations of the QA system. Specifically, the informational content relates to the service ordered to restore the patients' health (i.e., the medical care outcome). Furthermore, where regulatory control employs sanction to enforce the expectations contained in

rules and regulations, control by mutual response permits the physician to employ his or her own discretion in deciding it and how to use the expectation implicit in the feedback. The intent of the feedback is to provide the physician with information about the service ordered that he or she can use in the decision-making process, not to provide rules to replace this process.

The argument that mutual adjustment is more likely to achieve control in QA systems is a result of the intensive technology necessary to cope with the reciprocal interdependence of therapeutic tasks and the patient in an acute hospital environment. This interdependence makes therapeutic tasks what William Scott terms "active tasks": activities performed against an object (in this case, a hospitalized patient) offering variable and unpredictable response to the desired outcomes of the activities.⁷⁵ In other words, cause and effect between the process and outcome of care is uncertain and dynamic. Each patient has unique needs, and a hospital must offer custom services designed to meet these needs, and achieve the desired patient outcome. In these individually varying situations, unlike long-linked technology, the most appropriate method of controlling task performance is to permit individual workers to exercise discretion in handling their tasks:

The proportion of errors associated with performing active tasks can be reduced by allowing individual performers to assess the amount of resistance [to achieving the desired patient outcome] with which they are confronted at a given time and to adjust their activities accordingly.⁷⁶

To the extent that this discretion is permitted, subdivision of these tasks among several individuals is not desirable according to Scott. Similarly, a regulatory mechanism to coordinate and control these tasks activities of a regulatory control mechanism may well be "inappropriate to meet the particular amount of resistance encountered at a given time, [thus] standard approaches to

active tasks will entail a high proportion of errors or failures."⁷⁷ The regulatory approach to QA would thus fail because of incongruity with the active tasks and reciprocal interdependence of the therapeutic process of caring for hospitalized patients. Instead, considerable discretion, congruent with the amount of resistance encountered in the task, should be permitted to physicians in selecting the task activities appropriate for providing quality health care.

Studies Within the Military Health Care Sector

Within the military there are few studies available in the literature. O'Brien, King, and Mangelsdorff looked at the feasibility of the Army Medical Department (AMEDD) constructing a list of Quality of Care Indicators with which it could monitor the care given in its hospital system. They concluded that rather than constructing a single list of indicators the AMEDD should utilize automated patient data systems to allow the construction of varying lists of indicators tailored to the unique needs of individual users. The study also concluded that the management of quality assurance programs at the MEDCOM level requires different management techniques than previously envisioned by the AMED.⁷⁸

Piper determined the need for a Quality Assurance organization structure within the health care institutions to meet JCAH quality assurance standards. To determine the need, he distributed questionnaires to hospital staff and Chief Executive Officers (CEO) of hospitals within the United States. As a result of his study, Piper recommended that an institutionalized education program be developed to improve the staffs level of awareness toward quality assurance. Additionally, he recommended a quality assurance coordinator as part of the

organization structure element leading to the development of a QA department within five years.⁷⁹ Baker evaluated the current QA reporting, documentation, and the problem identification-prioritization-resolution system at Kenner Army Community Hospital against JCAH standards and Health Services Command (HSC) regulations, identified areas of noncompliance, and recommended policies and procedures to correct these deficiencies.⁸⁰ Baker also evaluated patient perceptions and staff opinions as to the value of these perceptions in QA activities.⁸¹

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CHAPTER III

DISCUSSION

Chapter I of this paper dealt with the development of the problem and the problem analysis which ascertained the problem to be the determination of the optimal feasible model for the quality assurance/risk management program at Naval Hospital, Bethesda. Additionally, criteria were designed with which to evaluate both the existing and the proposed program. These criteria were:

1. The QA/RM program shall meet the standards set forth by JCAH in their Accreditation Manual for Hospitals.
2. The QA/RM program shall meet the requirements set forth in BUMED Instruction 6320.62 by Naval Medical Command.
3. There shall be 100% compliance by all departments/divisions within Naval Hospital, Bethesda in maintaining the tracking system for QA/RM problems.
4. The QA/RM program shall result in less than 2% of the QA/RM problems forwarded to the QA/RM Committee being deemed by the Committee as having been solvable at the department or directorate level.

Chapter II consisted of a through literature review of the pertinent areas of quality assurance applicable to the problem. The knowledge gained during the literature review will now be applied during the discussion of the existing and proposed program. From this foundation, Chapter IV will cover the conclusions and recommendations drawn from the prior chapters.

General Information

The Naval Hospital, Bethesda is a complex, multi-specialty, tertiary care facility located in the metropolitan Washington, D.C. area. The hospital, with 544 beds and twenty outpatient clinics, requires more than 2,000 personnel to operate efficiently. A breakdown of professional, technical, skilled, and unskilled labor requirements follows:

Military Enlisted Personnel

397 General service hospital corpsmen	12 ENT technicians
14 Cardio-pulmonary technicians	35 X-ray technicians
17 Ocular technicians	28 Pharmacy technicians
9 Physical Therapy technicians	5 EEG technicians
42 Operating Room technicians	7 Urology technicians
39 Neuropsychiatric technicians	3 Dermatology technicians
101 Laboratory technicians	8 Dental technicians
9 Respiratory Therapy technicians	43 Other technicians
6 Nuclear Medicine technicians	8 Other Enlisted

Military Officer Personnel

408 Physicians	12 Dentists
185 Nurses	8 Chaplains
4 Physician Assistants	4 Dietitians
20 Health Care Administrators	6 Optometrists
9 Therapists (PT/OT)	11 Pharmacists
14 Medical Technologists	16 Psychologists
4 Radiation Specialists	

Civilian Personnel

164 Nurses	15 Social Workers
11 Nurse Practitioners	44 LPNs
49 Medical Technologists	10 Pharmacists
259 Other professional/clerical	142 Skilled/Unskilled labor

Naval Hospital, Bethesda also functions as a primary receiving facility for patients requiring special care referred from Europe and the northeastern United States. Annual workload for the hospital included more than 674,500 ambulatory visits, more than 177,000 inpatient days, more than 1,000 births, and more than 6,000 surgical procedures during calendar year 1982.

Due to the size and complexity of the hospital, the number of personnel involved, and the workload of the facility, the quality assurance/risk management program has become a major task. JCAH states "The hospital shall demonstrate a consistent endeavor to deliver patient care that is optimal within available resources and consistent with achievable goals. A major component in the application of this principle is the operation of a quality

assurance program."¹ To fulfill this principle JCAH's standard states "There shall be evidence of a well-defined, organized program designed to enhance patient care through the ongoing objective assessment of important aspects of patient care and the correction of identified problems."² Additionally, Naval Medical Command has issued the policy statement, "Each medical center, hospital and clinic shall demonstrate a consistent endeavor to deliver health care that is optimal, within available resources, and consistent with the mission of the command."³ Charged with meeting the standards of, and being accredited by JCAH, Naval Hospital, Bethesda has faced a tremendous task.⁴ The evolution of the QA/RM plans can be seen in the pertinent instructions in appendices D, E, and F. An additional influence on the evolution of the program was the difficulty with the JCAH Survey in November 1981.

Existing QA/RM Program

To understand the existing QA/RM program, the quality assurance/risk management organizational structure pre-reorganization of the Navy Medical Department must be contrasted to the organization of the QA/RM program after the reorganization. Pre-reorganization, the Quality Assurance/Risk Management Program was coordinated by a Quality Assurance Coordinating Committee consisting of the Director of Clinical Service, Director of Administrative Services, Chief of Nursing Service and such other members as might be appointed by the Commanding Officer. Copies of all minutes of the various Department/Service meetings were forwarded to the committee for monitoring, assessment and making recommendations, as necessary, to the Commanding Officer for appropriate action. All minutes of the various committees and reviews under the sections of the surveillance activities, regional activities, safety activities, and risk management activities, as seen in appendix G, were

forwarded to the committee for monitoring, assessment, and recommendations, as necessary, to the Commanding Officer for appropriate action. The Committee was assisted by a Quality Assurance Coordinator.

By October, 1982, due to the difficulty with the November, 1981, JCAH Survey and the reorganization of the Navy Medical Department in October, 1982, the organization of the QA/Rm program had evolved to a QA/RM Committee consisting of the QA Director as chairman, the Director of Medical Services, the Director of Surgical Services, the Director of Nursing Services, Director of Ancillary Services, and the Director of Hospital Administration. Copies of all minutes of the various Department/Branch meetings are forwarded through the Directorates to the Command QA/Rm office staff with documentation of QA/RM problems identified and corrected or identified and referred to the QA/RM Committee as seen in appendix H. The military staff of the Q.A. office are special assistants of the Commanding Officer and report directly to him in all QA/RM matters. The staff serves as advisors to the directors, department heads, and advises and investigates for the QA/RM Committee and the Commanding Officer. Only with approval of the Commanding Officer or Executive Officer will the QA staff investigate problems on the department or directorate level. The office is tasked with ensuring compliance with all Navy Department, Naval Medical Command, Naval Hospital and JCAH quality assurance standards are being adhered. The QA staff also oversees the JCAH accreditation process. The staff has full access to all minutes, reports, command files and meetings of the Naval Hospital and full access to all hospital spaces.

The QA Committee initiates QA investigations when necessary, acts upon problems referred from either the Directors or the Commanding Officer, and provides the Executive Committee of the Medical Staff with monthly reports. The committee has a representative from each directorate and has whatever

inhouse or outhouse consultants that are required. The Committee meets monthly. Any problems which cannot be corrected by the Committee are referred to the Commanding Officer with documentation stating why the problem cannot be corrected on lower levels.

Following is how a problem, once identified is put into the tracking system. The problem is documented through the entire process. Copies of documentation must be provided to the area identifying the problems from all levels of the QA ladder.

1. Quality Assurance problems are identified by all members of the staff and users. Most problems originate at the Department level. Documentation begins at this level using the format demonstrated in appendix I. Problems identified at the Department level are noted in the monthly staff meeting minutes with status and action being noted. Problems are then listed on the QA Problem Status Records shown in appendix J. and included with the monthly report. The monthly report with the problem flow sheet is then submitted to the Department Head's Director.

2. The Directors then review the submitted monthly reports and attempt to correct problems referred by the Department Heads. This action is the most important in correcting problems in a speedy manner. Communication between the Directors should usually get most problems corrected. The Enlisted QA Coordinator assigned to the Director makes a list using the QA Problem Status Record of all problems referred to the Director by his Department Heads. The list is reviewed by the Director weekly. All actions taken by the Director must be documented and a copy given to the referring department. Problems that cannot be corrected by the Director will be forwarded to the QA office for investigation and possible action or referral to the QA/RM Committee. The flow of this process is depicted in figure 1.

3. The QA/RM Office then reviews all problems submitted and investigates those problems being reviewed by the QA/RM Committee. Those problems that can be handled and corrected by the QA/RM staff using the authority granted to it by the Command are documented with the steps taken to correct the problem. The documentation is then reviewed by the QA/RM Committee at its next scheduled meeting. Problems not corrected by the staff are put on the QA/RM Committee agenda. The Committee should take an aggressive problem solving approach and all actions are documented. Results of the Committee are forwarded to the Commanding Officer. All problems not resolved by the Committee are forwarded to the Commanding Officer with all documentation. This process is depicted in figure 2.

4. The Commanding Officer is the final step in the QA/RM process. Actions taken at this level are final.

**FLOW CHART
SERVICE
QUALITY ASSURANCE PROGRAMS**

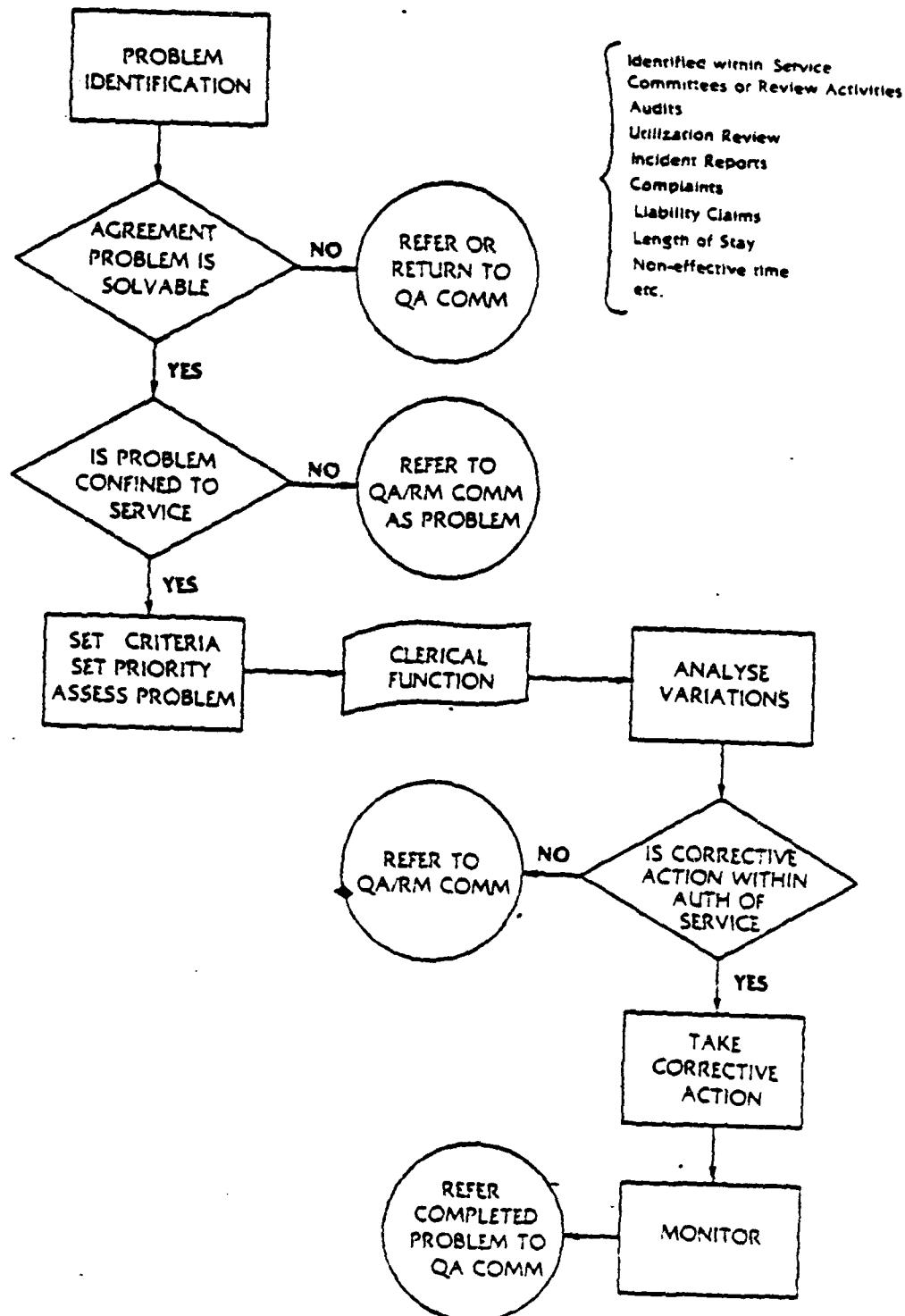


Figure 1

FLOW CHART

QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE

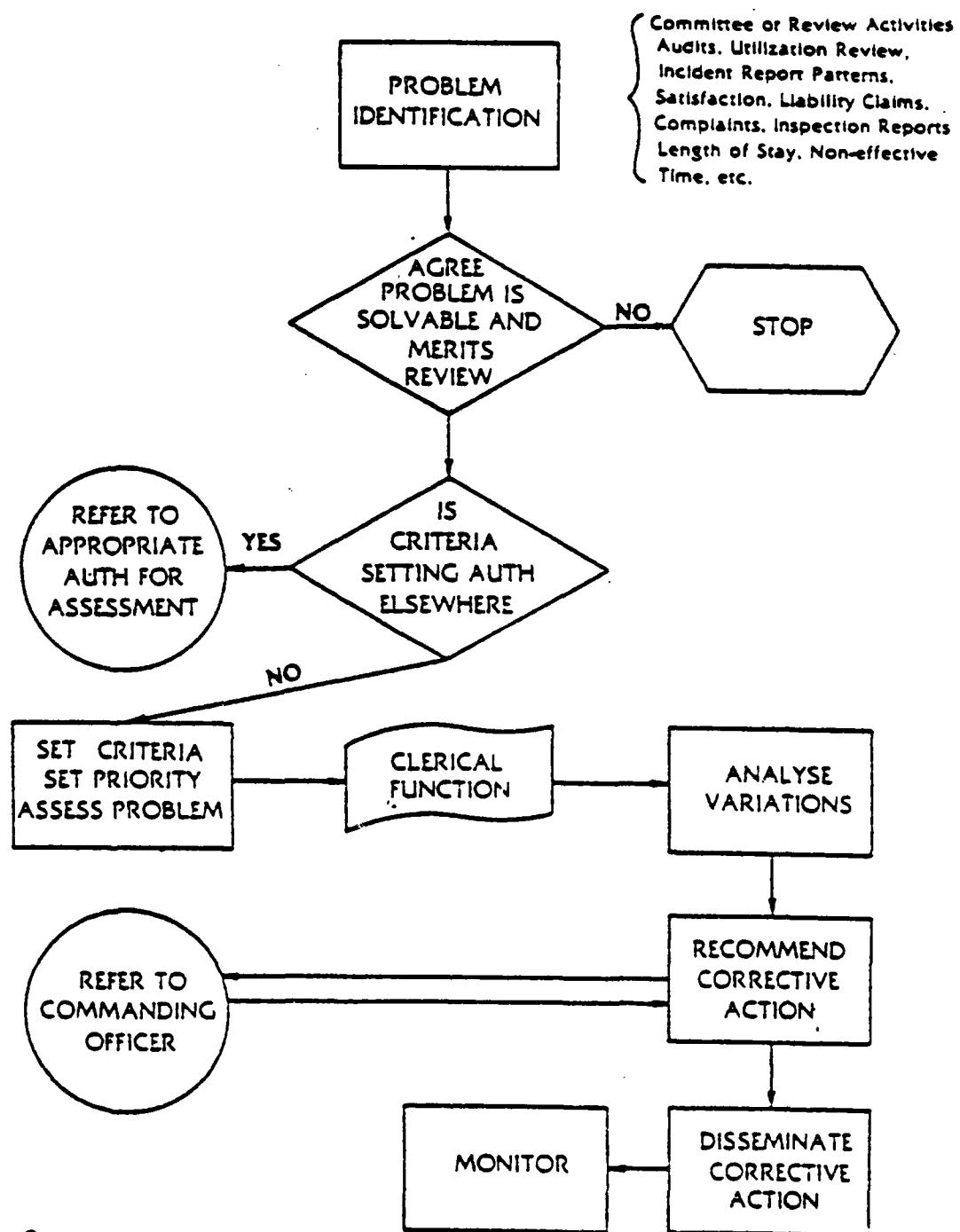


Figure 2

The aforementioned quality assurance flow cycle depicts the QA/RM Program as structured in the QA/RM Plan for Naval Hospital, Bethesda. If the plan is compared with five essential components of a sound quality assurance program as stated in the JCAH Accreditation Manual, on paper the plan could be said to meet the requirements as stated below:⁵

1. Identification of potential problems, or related concerns, in the care of patients.
2. Objective assessment of the cause and scope of problems or concerns, including the determination of priorities for both investigating and resolving problems. Ordinarily, priorities shall be related to the degree of impact on patient care that can be expected if the problem remains unresolved.
3. Implementation by appropriate individuals or through designated mechanisms of decisions or actions that are designed to eliminate, insofar as possible, identified problems.
4. Monitoring activities designed to assure that the desired result has been achieved and sustained.
5. Documentation that reasonably substantiates the effectiveness of the overall program to enhance patient care and to assure sound clinical performance.

However, the manual does not describe how to achieve and manage the program. This is where the existing program did not meet the full intent of the JCAH standards. The existing program in actuality was not resulting in "implementation by appropriate individuals or through designated mechanisms of decisions or actions that are designated to eliminate, insofar as possible, identified problems."⁶ Instead, the problems were being identified by the department/branch, forwarded to the directorate, and usually then forwarded to the QA/RM Committee without any action or staffing work having been done. It evolved into a "pass-the-buck" situation with all items being forwarded to the QA/RM Committee, including those that could have been handled on the department/branch or directorate level. Therefore, Criterion 1 of this study was not being met by the existing QA/RM Program.

Criterion 2 of this study required that the program meet the requirements set forth in BUMEDINSTRUCTION 6320.62. The requirements are as follows:⁷

1. A comprehensive systems approach to developing and maintaining a quality assurance/risk management program.
2. A problem focused approach for reviewing and evaluating patient care and clinical performance.
3. Integration/coordination of all quality review assessment activities by services to minimize duplication, enhance communication, and reduce cost.
4. An annual program assessment.
5. Evidence of improvement in patient care and/or clinical performance.

Here again, the existing program on paper meets the requirements, but not in actuality. Requirement 3 is not met due to the department/branches and directorates making little effort to solve their problems and forwarding everything to the QA/RM Committee for resolution.

Criterion 3 of this study required 100% compliance by all departments/divisions within Naval Hospital, Bethesda in maintaining the tracking system for QA/RM problems. To determine compliance, it was decided to sample the departments/branches within Naval Hospital, Bethesda and on the basis of documents determine whether the tracking was done. It was determined to use the Directorate of Ancillary Services as the sample. This directorate encompasses Laboratory Services, Pastoral Care, Physical Therapy/Occupational Therapy, Radiology/Nuclear Medicine/Radiation Oncology, Social Work, and Pharmacy. Due to the size and complexity of services covered by the directorate, it was felt that it would serve as a good estimator. Each department/branch and directorate is required to submit a Quality Assurance Problem Status Record (PSR) as seen in appendix I with the minutes of the monthly meetings. These status reports were studied. For the departments/branches, it was

determined that of the 46 problems found on the status reports between August 1983 and October 1983, 10 were lost from the tracking system for at least one month or completely (21.7%). Additionally, of the problems referred to the directorate, two problems were not picked up by the directorate in its status report. Therefore, the existing plan does not meet Criterion 3 of this study.

In order to determine compliance with Criterion 4, less than 2% the QA/RM problems forwarded to the QA/RM Committee being deemed by the Committee as having been solvable at the department or directorate level; the minutes of the QA/RM Committee meetings of August 1983 to October 1983 were reviewed. Of the 19 new problems referred to the committee in this time frame, 12 (63.2%) were referred by the committee back to the directorate or department. This does not meet Criterion 4.

Proposed QA/RM Program

After analyzing the existing QA/RM Program and determining that the program did not meet the criteria of this study, it was necessary to determine what was needed to bring the program into compliance. It was determined that the main problem area was the centralized program. Therefore, it was felt that the optimal model would be one of decentralization of the QA/RM Program as reflected in figure 3. This model would lend itself to a more efficient tracking mechanism of QA/RM problems and referral to the QA/RM Committee. This should result in more action being taken at the lowest level possible within the organization. Additionally, it was decided that there should be a designated person within the office of the Director of each directorate, who would be responsible for the tracking and documentation of quality assurance problems within the directorate. Only the quality assurance problems determined to be

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PROPOSED SERVICE
QUALITY ASSURANCE PROGRAMS

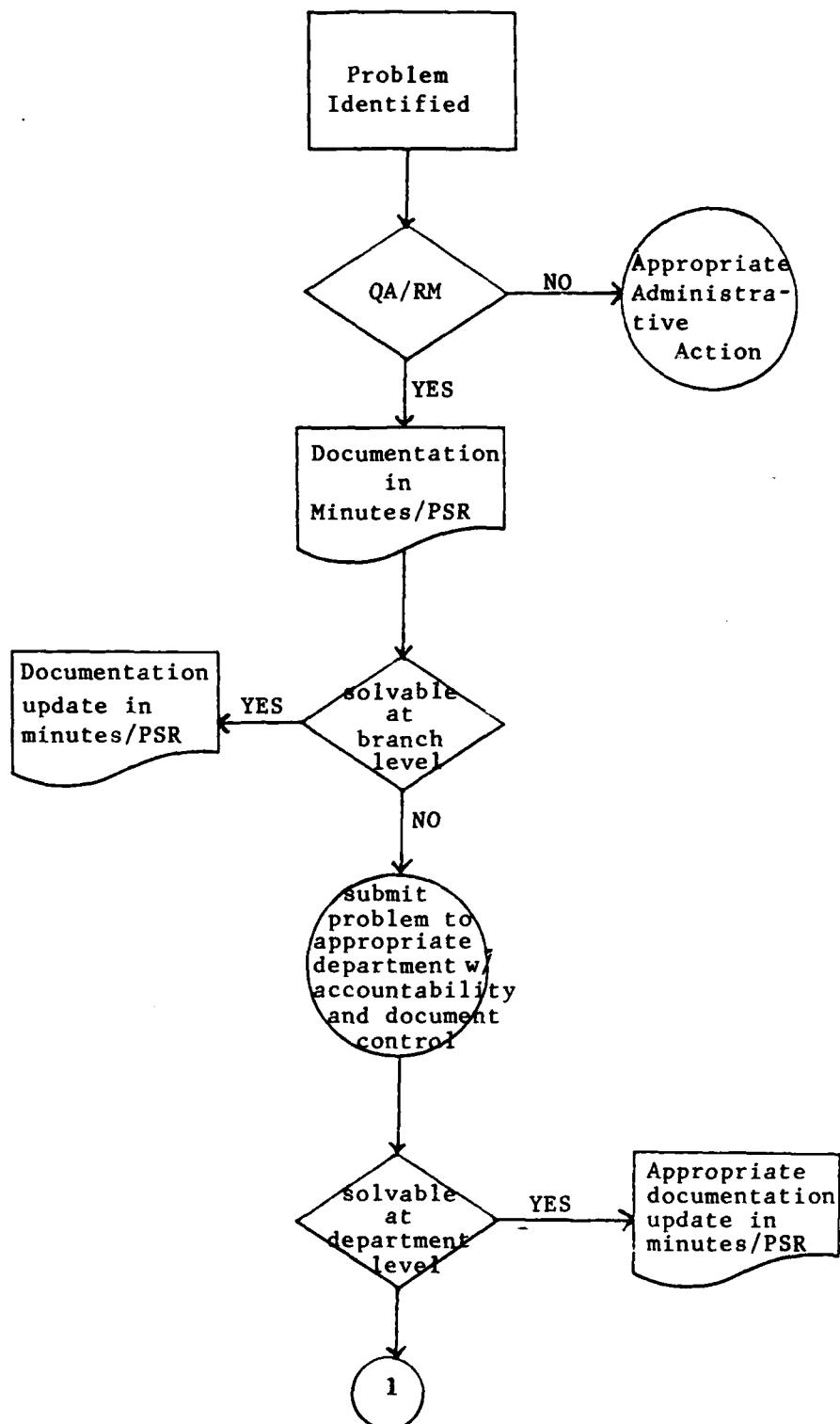
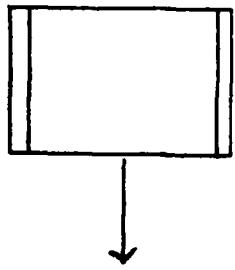
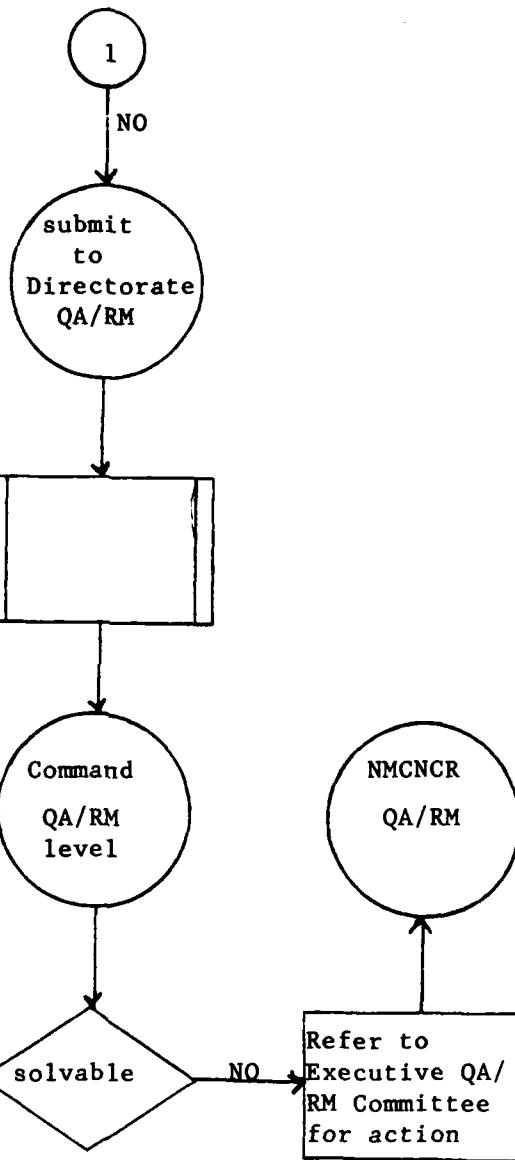


Figure 3



1. Receive problem.
2. Place on document control.
3. Document in minutes/PSR.
4. Work on problem solving.
5. Monitor progress & provide updates on PSR until resolved.
6. Submit monthly update (minutes) of all Department PSR to command QA/RM.
7. If problem not resolvable at directorate level or crosses, refer to command QA/RM



beyond the resources of the directorate to handle and requiring command action would be forwarded. With each directorate responsible for action, documentation, and tracking of the problems identified, the tasking is decentralized allowing the QA/RM Office to concentrate on the higher priority issues to the command and a better utilization of the time and personnel of the office.

After approval of the proposed system, a meeting was held on 07 September 1983 with the Directorate QA Coordinators outlining the new responsibilities and actions to be taken. The proposed system on paper meets the criteria determined for this study. However, in order to determine the effectiveness of the system, sampling of documents was necessary. Again, the Directorate of Ancillary Services was utilized. After analysis of the minutes and problem status reports, it was determined that of the 11 new problems documented by the departments within the directorate, between November 1983 and February 1984 only 1 problem (9.1%) was dropped out of the status report without reflecting completion or referral. Additionally, it was determined that of the 3 new problems referred to the directorate, none were lost from the tracking mechanism. Furthermore, no problems referred to QA/RM Committee were determined by the committee to be inappropriate referrals and returned to the directorate. It is felt the proposed system meets the criteria of this study.

1 Joint Commission on Accreditation of Hospitals, Accreditation Manual for Hospitals, 1983 ed. (Chicago: Joint Commission on Accreditation of Hospitals, 1982), p. 151.

2

Ibid.

3

U.S., Department of the Navy, Bureau of Medicine and Surgery, Health Care Quality Assurance/Risk Management Program, BUMEDINST 6320.62, Washington, D.C., 29 May 1981, p. 1.

4

Ibid.

5

JCAH, Accreditation Manual for Hospitals, p. 152.

6

Ibid.

7

U.S., Department of the Navy, Bureau of Medicine and Surgery, Health Care

Quality Assurance/Risk Management Program, BUMEDINST 6320.62, Washington,
D.C., 29 May 1981, pp. viii-ix.

CHAPTER IV
CONCLUSIONS AND RECOMMENDATIONS

Conclusions

A comprehensive study of the current literature on quality assurance/risk management has been conducted. A tremendous amount of literature is available. Therefore, only the areas of trends and factors leading to the development of quality assurance, legislative and organizational influence on quality assurance, quality of care, quality assurance in health care, evaluation, organizations, structure, control, and studies within the military health care system were covered. An analysis of the existing QA/RM Program was done utilizing the predetermined criteria of this study. After determining the non-compliance of the program, the weak points of the program were analyzed leading to the model of the proposed QA/RM Program. On paper the proposed model met the predetermined criteria, however, a sampling of the documents and records was done. On this basis the proposed model was determined to meet the criteria of the study. However, this determination was based on a sampling of one directorate and four months of documents of the department/branch, directorate, and QA/RM Committee.

Recommendations

Because of the short time frame of the analysis of the proposed QA/RM Program, it is recommended that the proposed program be reassessed after six months, utilizing the established criteria. Additionally, in order to maintain control within the program, the Command QA/RM Office must set up monitoring of the records of each Directorate QA Coordinator to establish compliance with the new

program.

Although the decentralization of the tracking of the departmental and directorate QA problems will decrease the tremendous load in the QA/RM office, the office must still track the problems referred to the QA/RM Committee, coordinate activities, and monitor the work done within the directorates. Therefore, it is recommended that a numbering system be incorporated in the problem status reports of the departmental, directorate, and command. This would facilitate monitoring and tracking of identified problems. It is suggested that the Command QA Department issue specific memorandum guidance on a master numbering system for use by all departments reporting quality assurance problems via monthly meeting minutes. The system could utilize the departments' organizational code (TRI-SARD: 52), the year the problem was identified (1984), the chronological order of its being recorded, and the level at which the problem is accepted for resolution and monitoring (Dept., Dir., or Com.), e.g., "TRISARD Implementation Status Report response strategy" 52-84-01-Com. The master numbering system has the added benefit of being easily converted to a computerized tracking system.

Because of the size and complexity of the requirements of the QA/RM Program at Naval Hospital Bethesda, it is felt that a computerized system is a requirement to effectively coordinate, integrate, and monitor the quality assurance activities of this hospital. With computer support, the quality of the QA process could be stressed by the command QA office rather than the tremendous manual effort.

APPENDICES

APPENDIX A

Definitions

The following definitions are offered to help clarify the terms used in the study.

Ambulatory Health Care Center: A public or private organizational unit which provides directly or through contractual arrangements health care services to meet the needs of non-institutionalized or non-housebound patients.

Assessment: An evaluation of how all objectives have been achieved according to specified standards and criteria.

Categories: General organizational structures which can be used to define patient populations (e.g., nutritional diagnosis, developmental stages).

Characteristics: Refers to the distinguishing features of the model components.

Competency: Is the minimum knowledge, skills, affective behavior, and/or judgment which a person is certified to posses based on a set of criteria and level of expectation.

Criteria (criterion): Designates variables selected as relevant indicators of the quality of health care; measures by which health care is judged as good; predetermined elements against which aspects of the quality of health service can be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Effectiveness: The extent to which pre-established objectives are attained as a result of an activity.

Efficiency: Is the attainment of quality health care reviewed in relationship to the manpower, supply, equipment, space and other resources of the provider and appropriateness, acceptability and cost to the consumer.

Health Care: Consists of elements concerning the health of an individual including environment, nutrition and patient care.

Health Care Consumer: An individual who is a user of health care services or a potential patient and whose primary source of income is not based on the delivery of health care or health care products.

Non-Physician Health Care Practitioners: Those health professionals who (a) do not hold a Doctor of Medicine or Doctor of Osteopathy Degree; (b) are qualified by education, experience and/or licensure to practice their profession; and (c) are involved in the delivery of direct patient care or services in hospitals and other institutional or non-institutional settings.

Norms: Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over time.

Outcome: Is the measurable end-result of care that is shown by the change in the state of health of the client after an intervention is given.

Patient: Any recipient of health care services.

Process: Is the sequence of events and activities involved in the delivery of health care.

Peer Review: The formal assessment of health care practitioners of the quality and efficiency of services rendered or provided by other members of their profession.

Quality: A group of properties characterized as "good"; the degree of excellence.

Quality Assurance: Activities performed to determine the extent to which a phenomenon fulfills certain values and activities done to achieve changes in practice that will assure the highest level of performance.

Quality Assurance Program: One that includes the establishment of a set of standards and criteria, and for the assessment of the level of practice in terms of those standards and criteria. It allows for the actual change in the

behavior of the professionals who will translate the findings of assessment into changed behavior that is useful socially and of benefit to the patient.

Quality-of-Care: Involves two concepts: The quality of the technical care, and the quality of the art of care.

Technical Care: Refers to the adequacy of the diagnostic and therapeutic process.

Art of Care: Relates to the milieu, manner, and behavior of the provider in the delivery of care and communicating with the patient.

Reliability: Consistency with which a measure yields similar outcomes or repeated measures of the same phenomenon.

Standard: An established measure of quality or value, an example for comparison and a criterion of excellence.

Structure: Includes consideration of the purpose of the institution, agency or program, and its legal authority to carry out the mission; organizational characteristics; fiscal resources and management; qualifications of health professionals and other workers; physical facilities and equipment and status with regard to accreditation, certification or approved by appropriate voluntary or governmental bodies.

Validity: Degree to which a measurement has produced a "true" representation of the phenomenon being measured without the influence of other phenomena.

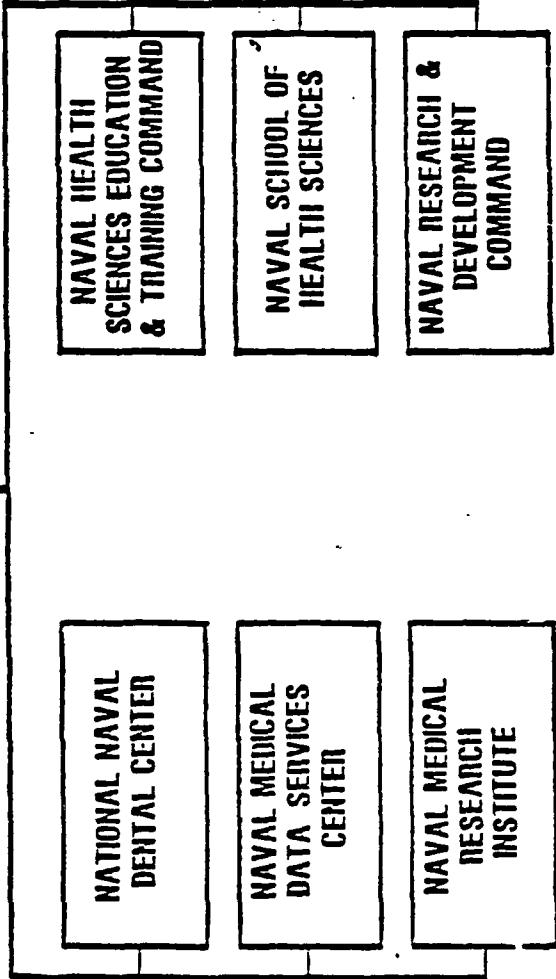
APPENDIX B

**National Naval Medicine Center
23 October 1981
Organizational Charts**

AREA COORDINATION

NAVAL DISTRICT
WASHINGTON, D.C.

NATIONAL NAVAL
MEDICAL CENTER



DATE:	APPROVED:	NATIONAL NAVAL MEDICAL CENTER Bethesda, Maryland 20814	CHART NUMBER: 2
9 OCT 1981	<i>D. L. Clegg Jr.</i> COMMANDING OFFICER		

TENANT COMMANDS						CHART NUMBER:	
NATIONAL NAVAL MEDICAL CENTER		NAVY EXCHANGE BETHESDA (NAVAL DISTRICT WASH., DC)	PHYSICAL EVALUATION BOARD ONDE	RESIDENT AGENT NAVAL INVESTIGATIVE SERVICE, ONI	PERSONNEL SUPPORT ACTIVITY DETACHMENT, PSA, WDC		
NAVAL HEALTH SCIENCES EDUCATION & TRAINING COMMAND		CONSOLIDATED CIVILIAN PERSONNEL OFFICE - NORTHWEST	NAVAL RESEARCH AND DEVELOPMENT COMMAND	ARMED FORCES RADIO-BIOLOGY RESEARCH INSTITUTE, DMA	NAVAL MEDICAL DATA SERVICES CENTER	NAVAL REGIONAL FINANCE CENTER, BRANCH OFFICE, WASH., D.C.	
NATIONAL NAVAL DENTAL CENTER		NAVAL SCHOOL OF HEALTH SCIENCES	NAVAL MEDICAL RESEARCH INSTITUTE				NATIONAL NAVAL MEDICAL CENTER BETHESDA, MARYLAND 20014
							APPROVED: <i>D. B. Creed, Jr.</i> COMMANDING OFFICER
DATE: 23 OCT 1961							3

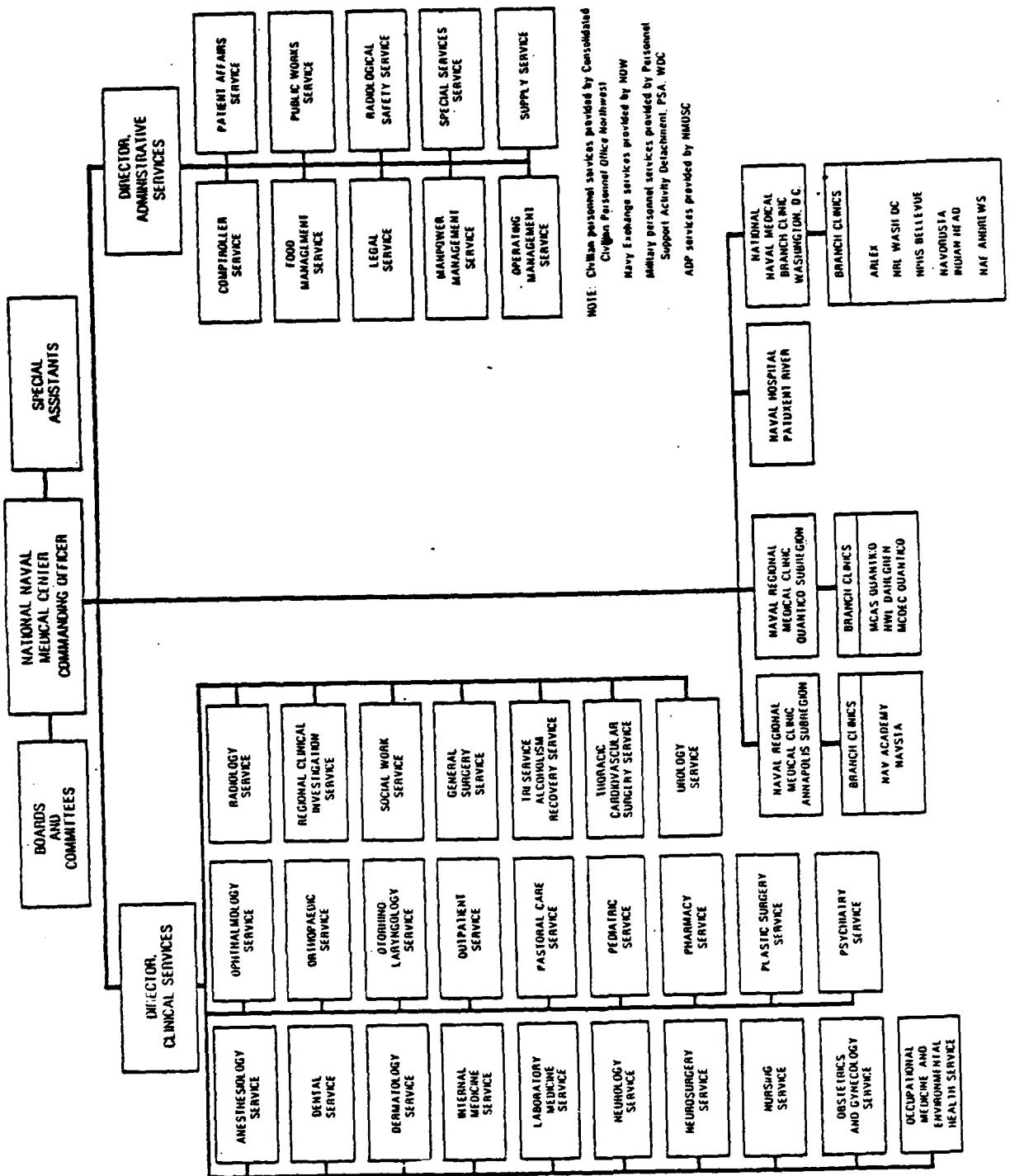


CHART NUMBER:		1	
DATE:	APPROVED:	NATIONAL NAVAL MEDICAL CENTER BETHESDA, MARYLAND 20014	
29 OCT 1971	<i>D. B. Clegg Jr.</i>	COMMANDING OFFICER	

APPENDIX C

**Naval Hospital, Bethesda
15 December 1982
Organizational Charts**

AREA COORDINATION

NAVAL DISTRICT
WASHINGTON, D.C.

NAVAL MEDICAL COMMAND,
NATIONAL CAPITAL REGION

NAVAL HOSPITAL
BETHESDA, MD.

NAVAL HOSPITAL
BETHESDA, MARYLAND 20814

CHART NUMBER:
2

APPROVED:
D. R. Green
COMMANDING OFFICER
15 DEC 1982

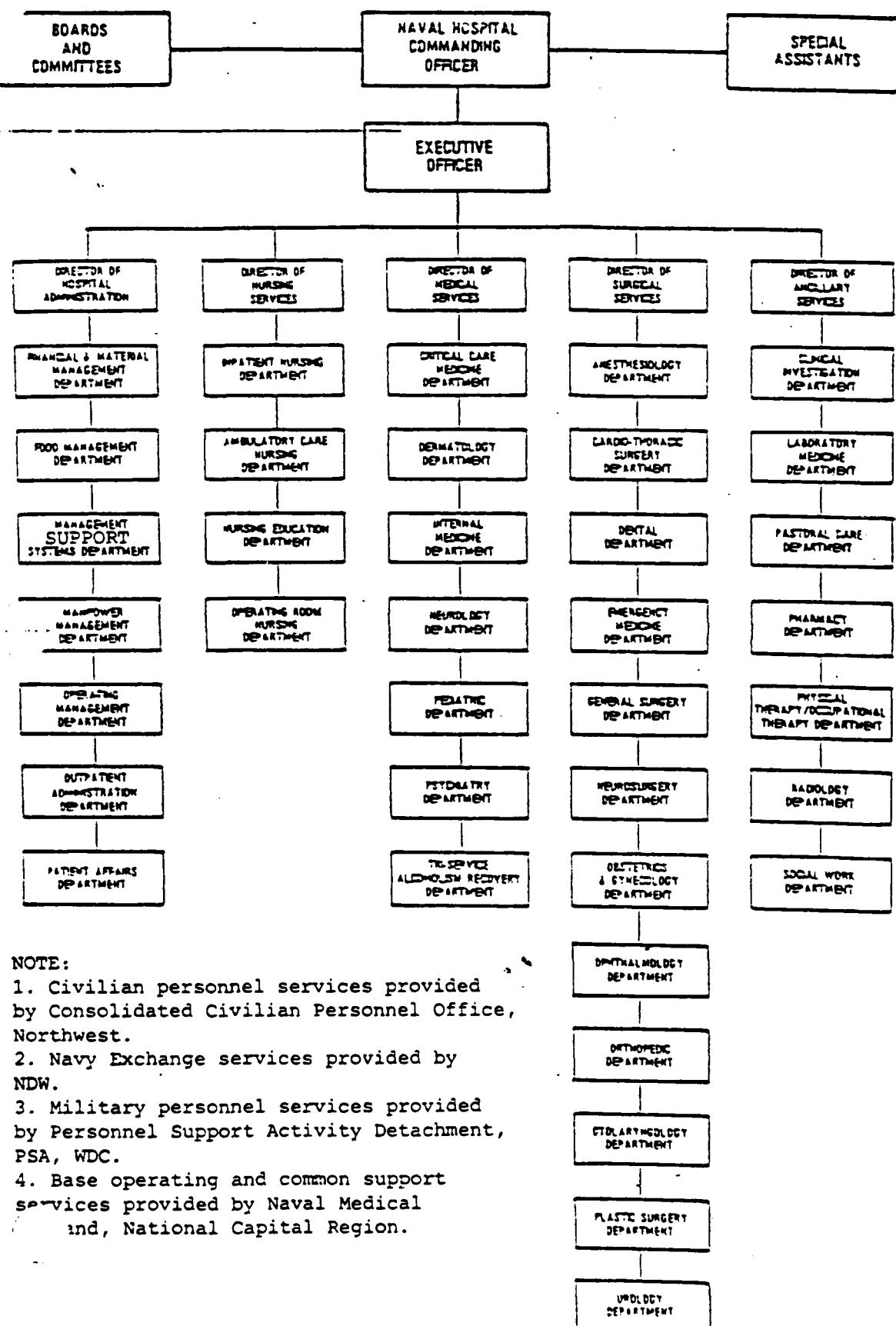


CHART NUMBER:
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NAVAL HOSPITAL
BETHESDA, MARYLAND 20814

APPROVED:

J. J. Dunn
COMMANDING OFFICER

16
5 DEC 1962

APPENDIX D

**NNMC INSTRUCTION 6320.14 B
Quality Assurance Program
2 February 1981**



NATIONAL NAVAL MEDICAL CENTER

BETHESDA, MARYLAND 20014

IN REPLY REFER TO
NNMCINST 6320.14B
NNMC:CO2A:y1
2 February 1981

NNMC INSTRUCTION 6320.14B

From: Commanding Officer, National Naval Medical Center, Bethesda, Maryland 20014

Subj: Quality Assurance Program

Ref: (a) Accreditation Manual for Hospitals, JCAH, 1981
(b) The Quality Assurance Guide, JCAH, 1980
(c) BUMEDINST 6320.54, Medical Care Evaluation

Encl: (1) National Naval Medical Center, Bethesda, Maryland
Quality Assurance Program
(2) National Naval Medical Center, Bethesda, Maryland
Quality Assurance Organization Chart

1. Purpose. To insure the highest quality of patient care is provided throughout the National Naval Medical Center through implementation of a comprehensive, coordinated, and integrated Quality Assurance Program in accordance with references (a) through (c) and enclosures (1) and (2).

2. Cancellation. NNMCINST 6320.14A

3. Background. The Joint Commission on Accreditation of Hospitals requires that a hospital demonstrate a consistent endeavor to enhance the delivery of quality patient care that is optimal within available resources and consistent with achievable goals. To demonstrate compliance with this requirement, each medical care facility must have a written plan which defines a comprehensive organized program designed to coordinate all quality assessment activities, provide for identification and the correction of identified problems, follow-up on corrective action taken and at least an annual evaluation of the plan.

4. Action. The Quality Assurance Program outlined in enclosures (1) and (2) is hereby established as the official program for the National Naval Medical Center. Any command instructions or notices in conflict with this instruction will be modified to conform to the requirements of enclosures (1) and (2). In addition to the specific responsibilities and duties outlined in enclosure (1), the following general responsibilities exist in this program:

a. Chiefs of Service/Departmental Chairmen, and all other individuals in positions of authority will support and participate in the Quality Assurance Program to the fullest extent. In addition, they will ensure that personnel within their areas of responsibility are fully aware of the goals and objectives of the Quality Assurance Program as delineated in references (a) through (c) and as established by this instruction.

b. All staff members shall familiarize themselves with the requirements of the Quality Assurance Program and should report areas of concern through the chain of command for evaluation through the program established herein.

5. Evaluation. The Quality Assurance Program shall be reviewed, at least annually to assure that the program is operational, comprehensive, and effective in improving patient care, clinical, and administrative performance.



J. T. HORGAN

Distribution:

I.a., I.c., III, V.a.

NATIONAL NAVAL MEDICAL CENTER, BETHESDA, MARYLAND
QUALITY ASSURANCE PROGRAM

Purpose. The goal of the National Naval Medical Center's Quality Assurance Program is to maintain and enhance the delivery of quality health care that is optimal within available resources and consistent with achievable goals. This goal is to be achieved through analysis, review, and evaluation of clinical and administrative practices within the Hospital. The objectives of the Quality Assurance Program are to monitor, coordinate, and integrate quality assurance activities and to focus on accountability for such activities.

Scope/Comprehensiveness. Every person attached to and working at the National Naval Medical Center affects the quality of health care given either directly or indirectly. Therefore, it is everyone's responsibility to assist in identifying problems and effecting their solutions. The Chairmen/Chiefs of the Clinical Services and the Chiefs of the Administrative Services are responsible for an on-going, active program to identify, resolve if possible, and monitor results in their areas affecting the quality patient care.

Administration/Coordination. The Quality Assurance Program at the National Naval Medical Center shall be coordinated by a Quality Assurance Coordinating Committee consisting of the Director of Clinical Services, Director of Administrative Services, Chief of Nursing Service and such other members as may be appointed by the Commanding Officer. Copies of all minutes of the various Department/Service meetings will be forwarded to this committee for monitoring, assessment and for making recommendations, as necessary, to the Commanding Officer for appropriate action. All minutes of the various committees and reviews under the sections of the surveillance activities, regional activities, safety activities, and risk management activities, as delineated in enclosure (2), will be forwarded to this committee for monitoring, assessment, and recommendations, as necessary, to the Commanding Officer for appropriate action.

Responsibilities

Commanding Officer. The Commanding Officer has the sole power to approve or disapprove any decision or recommendation pertaining to health care at the National Naval Medical Center.

Executive Committee. The Executive Committee shall provide support for the Quality Assurance Program by ensuring staff compliance with recommendations that are essential to achieve the goals and objectives of the program.

Director of Clinical Services. The Director of Clinical Services shall be responsible for the operation of the Quality Assurance Program in the clinical services and shall meet at least monthly with the chiefs of clinical services to coordinate such matters.

Director of Administrative Services. The Director of Administrative Services shall be responsible for the operation of the Quality Assurance Program in the administrative services and shall meet at least monthly with the chiefs of administrative services to coordinate such matters.

Chiefs of Clinical/Administrative Services. Each Chief of Service shall establish and maintain an on-going quality assurance program within the service. The program shall be based upon pre-established criteria which shall be designed to identify departmental deficiencies in meeting quality standards. The quality review against these criteria shall be reported at least monthly to the appropriate director of services along with problem areas and corrective action. The Chairmen/Chiefs of the various services shall establish the priorities for problems which are unique to their service. If the problem cannot be resolved within the Department/Service and/or if the problem involves more than one service, the identified problem shall be referred to the Quality Assurance Coordinating Committee for their recommended prioritization and submission to the Commanding Officer for approval.

Quality Assurance Coordinating Committee. The Quality Assurance Coordinating Committee shall coordinate and integrate the quality assurance activities referred to them by the various committees, reviews, and departments.

Quality Assurance Coordinator. The Quality Assurance Coordinator shall assist the Quality Assurance Coordinating Committee in its staff functions.

Credentials Committee. The Credentials Committee shall review applications and determine qualifications for clinical staff privileges for purposes of education and problem resolution. This committee shall ensure that the mechanism for annual re-evaluation of credentials is carried out according to current instructions and shall report through the Director of Clinical Services to the Commanding Officer.

Quality Assurance Activities. The committees and reviews under the sections of the surveillance activities, regional activities, safety activities, and risk management activities shall report on-going quality assurance matters to the Quality Assurance Coordinating Committee.

Problem-Focused Approach. The National Naval Medical Center Quality Assurance Program is an on-going process designed to ensure quality and to identify problem areas upon which to focus corrective action. While there is no set method for problem identification, criteria used to define the problem must be valid. Once a problem has been identified, it must be prioritized and action taken to resolve it, if possible. It is recognized that all problems identified may not be amenable to solution due to factors such as lack of resources, federal regulations, etc. Problems which are amenable to solution and for which corrective actions are taken shall be evaluated to see that the corrective actions taken do indeed correct the problem. All problems and actions taken as a result shall be documented in appropriate minutes to provide follow-up and to provide a guide as to the status of the Quality Assurance Program and whether quality assurance efforts are successful. If the decision is made to take no corrective action in an identified problem area, the rationale for the decision must be documented.

Enclosure (1)

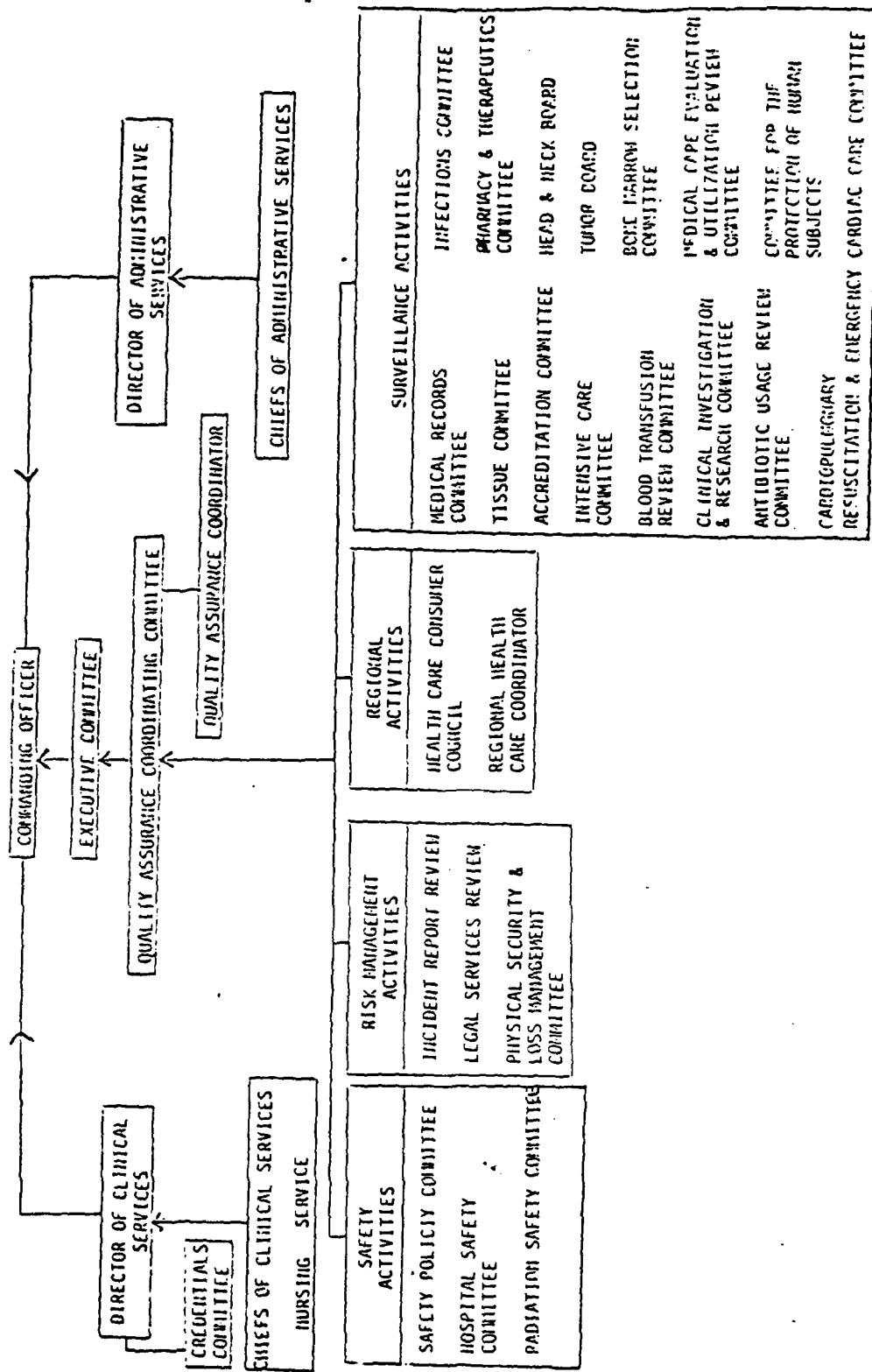
2 FEB 1981

Evaluation. The Quality Assurance Program shall be reviewed on a continuing basis and recommended changes may be forwarded to the Quality Assurance Coordinating Committee at any time. Annually, on the anniversary of this instruction, the program shall be reviewed formally by the Quality Assurance Coordinating Committee to assure that it is comprehensive and effective in improving clinical and administrative performance in providing the highest quality of health services to both outpatients and inpatients. A written report of the annual review shall be made to the Commanding Officer and shall be made a permanent part of the files of the Quality Assurance Coordinating Committee.

2 FEB 1991

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NATIONAL NAVAL MEDICAL CENTER, BETHESDA, MARYLAND
QUALITY ASSURANCE ORGANIZATION CHART



Enclosure (2)

APPENDIX E

NHBETH INSTRUCTION 6320.14
Quality Assurance/Risk Management
Program
28 October 1982



DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND 20814

IN REPLY REFER TO

NHBETHINST 6320.14
NH:OIA:JFP:me
28 October 1982

NHBETHINST 6320.14

From: Commanding Officer

Subj: Quality Assurance/Risk Management Program

Ref: (a) Accreditation Manual for Hospitals, JCAH
(b) BUMEDINST 6320.62

Encl: (1) Format for Departmental Minutes
(2) Q.A. Study Abstract
(3) Quality Assurance Problem Status Record
(4) Quality Assurance/Risk Management Program Problem Identification Sheet.

1. Purpose. This program is designed to enhance patient care at the Naval Hospital through the ongoing assessment of important aspects of patient care and the correction of identified problems as defined and explained in references (a) and (b). The main objective of this program is to monitor, coordinate, integrate and establish accountability for quality assurance. All departments (Clinical, Administrative, and Support), all medical disciplines and all staff members and health care practitioners, military and civilian, are required to participate.

2. Policy. Each section, branch, Department and Director shall demonstrate a consistent endeavor to deliver health care that is optimal, within available resources, and consistent with the mission of this command.

3. Definitions. The Quality Assurance/Risk Management Program is the plan for assuring the provisions of quality health care at the Naval Hospital, Bethesda. The Quality Assurance/Risk Management Program (henceforth referred to as the Q.A. program) should be:

- (a) Comprehensive
- (b) Flexible enough to permit innovation and variation in the approaches which are used to:

1. evaluate, in diverse instances, whether the "optimal attainable outcome" of health care has been realized;
2. identify problems which result in failure to attain this result and;
3. hasten and facilitate problem solution.

4. Scope.

- a. All Naval Hospital personnel have a direct or indirect impact upon the quality of health care rendered to patients. It is incumbent upon all to assist in the identification of health care related problems and in effecting solutions to problems.

Subj: Quality Assurance/Risk Management Program

b. The Heads of Departments are responsible for the continued identification and resolution (where practical) of problems affecting the quality of patient care within their areas of supervision and to continuously monitor the results of these efforts. All problems identified that are outside their areas of supervision and responsibility will be referred to the Director of the Service they come under for further investigation and corrective action.

c. Problems identified and addressed by Special Care Units within the hospital are reviewed by the appropriate Clinical Directors.

d. Identified problems which cannot be resolved at the Director level will be referred to the Q.A. Committee. The Director's Administrative Assistant or Q.A. Coordinator shall notify the Command Q.A. Office in writing before submitting problems to the Q.A. Committee to insure that necessary preliminary investigations are initiated.

e. All problems submitted to the Q.A. Committee, whether solved or unsolved will be forwarded to the Commanding Officer for review or further action.

f. Evaluation and review should be PROBLEM FOCUSED (i.e., should identify problems), should be effective in resolving problems and should not merely be intended to document how well care is delivered.

g. Documentation is mandatory in Quality Assurance. This documentation will be accomplished using the forms approved by the Command. Enclosure (1) is the only approved format for departmental minutes. The example provided will be adhered to by all Departments. This example provides guidelines which will be followed by all submitting Departments and all topics listed will be addressed. Other enclosures listed in enclosure (1) will be used. Enclosure (2) will be submitted anytime a Q.A./R.M. study is completed. This form provides documentation of required studies (e.g., radiology monthly retake rates, patient waiting times, medication studies, nursing service studies). Enclosure (3) will be submitted with all monthly minutes even if there are no problems identified in the monthly meeting. No changes are permitted in the format of these forms without prior approval of either the Q.A. staff or the Committee.

5. Problem Focused. The Q.A. program is intended to be dynamic, identifying problems upon which to focus corrective action, and ensuring the delivery of high quality health care. There is no single best method for problem identification. When guidelines are used against which to evaluate the quality of health care, they will be defined in writing and approved by the involved department, the Department Heads and the Q.A. Director. If the Q.A. Director questions any of the guidelines submitted, he will forward them to the full Q.A. Committee for approval. All guidelines will be reviewed annually. Having been identified, a problem will have a priority assigned to it on all levels and action taken to resolve it. Some problems will prove incapable of being resolved with available resources. These problems will have corrective actions applied and then will be periodically reviewed to assure that they remain active until resolved. A monitor will be assigned by name to these problems. All identified problems and all corrective actions taken will be documented in the appropriate minutes. Documentation will be such that one can clearly trace the method of problem identification. This includes the identified problem, the corrective actions undertaken and the follow-up results of those actions through a sequential review of the minutes. Enclosure (4) will be used to document problems within the Department and also

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Subj: Quality Assurance/Risk Management Program

being forwarded to the Q.A./R.M. Committee. Should a decision be made for any reason not to correct an identified problem the rationale for such a decision will be clearly documented.

6. Responsibilities.

1. Commanding Officer. The Commanding Officer of the Naval Hospital, Bethesda has the authority to approve or disapprove any decision or recommendation relating to health care provided at this facility.

2. The Directors. The Directors of Ancillary, Administrative, Nursing, Medicine and Surgery Services will provide support for the program by ensuring staff compliance with the goals and objectives of the Q.A. program. The Directors will ensure that all problems identified to them are recorded using the formats given in enclosures (3) and (4) and that no problem is inadvertently dropped short of being resolved. The Directors will ensure that any corrective action that can be taken at the Directorate level is initiated. Communication and documentation at this level is extremely important. Each Director will be assisted in the performance of their Q.A. functions by both their Administrative Assistants or Quality Assurance Coordinator and a full time E-4 or above Hospital Corps Q.A. Assistant. The Administrative or Q.A. Assistants to the Directors shall prioritize problems identified using a numerical system starting with one (1) which will be the most urgent problem and numbering down. The priority assigned will remain with the specific problem until it is completed.

3. Heads of Clinical and Administrative Departments. Each Department Head shall establish and maintain a Q.A. protocol which shall be submitted to the Q.A./R.M. Office for review and approval. Assessment of care, as determined by the protocol, and documented in the monthly minutes shall be reported to the appropriate Director with a copy to the Q.A. Office and shall include identified problems as well as corrective actions and their results. If the problem cannot be resolved within the service involved it shall be highlighted in yellow and referred to the Administrative Assistant of the areas Director. The Department Head will only use the reporting format used in enclosure (1) to document the monthly staff meeting.

4. Command Quality Assurance/Risk Management Office Staff. The military staff of the Q.A. Office are special assistants of the Commanding Officer and report directly to him in all Quality Assurance/Risk Management matters. The staff of this office will serve as advisors to the Directors, and the Department Heads, and as advisors to and investigators for the Q.A./R.M. Committee and the Commanding Officer. Only with the approval of the Commanding Officer or Executive Officer will the Q.A. staff investigate problems on the department or directorate level. This office will be tasked with ensuring all Navy Department, Naval Medical Command, Naval Hospital and JCAH quality assurance standards are being adhered to. The Q.A. staff will also oversee the JCAH accreditation process. The staff of this office will have full access to all minutes, reports, command files and meetings of the Naval Hospital and will have full access to all hospital spaces.

5. Quality Assurance/Risk Management Coordinator. The incumbent will coordinate all Q.A. assignments as far as education and training. The Q.A. coordinator will establish and maintain a Q.A./R.M. training program for the entire staff of the Naval Hospital. The coordinator is further tasked with establishing

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28 October 1982

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and maintaining a training program for MSC officers and senior enlisted members of the Hospital Corps in accreditation standards and JCAH procedures. If this position is vacant the training responsibilities will be jointly assumed by an officer of the Medical Service Corps who has received Q.A. training and the Q.A. Office Adminisitrative Assistant.

6. Quality Assurance/Risk Management Director. The Director of the Q.A. Program shall be a senior officer of the Medical Corps. As such, he or she will be responsible for the Q.A. staff and it's functions. The Q.A. Director shall be the Chairman of the Q.A./R.M. Committee and the officer in charge of the Q.A./R.M. Office. The Director is responsible for overseeing the entire Q.A./R.M. program at this command.

7. Quality Assurance/Risk Management Committee. The Q.A. Committee shall initiate Q.A. investigations where necessary; and shall act upon problems referred from either the Directors or the Commanding Officer. The Q.A. Committee will provide the Executive Committee of the Medical Staff with monthly reports. The committee shall have a representative from each Directorate and will have what ever inhouse or outside consultants that are required. The Committee shall meet monthly and will act upon all problems submitted to it. Any problems that cannot be corrected by the Committee will be referred to the Commanding Officer with documentation stating why the problem cannot be corrected on lower levels.

7. Committees Reporting To The Q.A./R.M. Committee.

The Credentials Committee shall obtain pertinent information regarding each health care practitioner excepting nurses and speech pathologists from the Q.A./R.M. staff prior to making a recommendation for annual re-certification of the practitioner. The Credentials Committee will provide the Executive Committee of the Medical Staff with copies of all decisions reached and a monthly report of any pending action.

8. The Q.A./R.M. Flow Cycle. The following is how a problem, once identified is put into the Q.A. tracking system. The problem will be documented through the entire process. Copies of documentation must be provided to the area identifying the problem from all levels of the Q.A. ladder.

1. Quality Assurance problems will be identified by all members of the staff and users. Most problems will originate at the Department Head level. Documentation must begin at this level using the format demonstrated in enclosure (4). Problems identified at the Department level will be noted in the monthly staff meeting report with status and action being noted. Problems will then be listed on enclosure (3) and included with the monthly report. The monthly report with the problem flow sheet attached will then be submitted to that Department Heads Director.

2. The Directors will then review the submitted monthly reports and will attempt to correct problems referred by the Department Heads. This action is probably the most important in correcting problems in a speedy manner. Communication between the Directors will usually get most problems corrected. The Enlisted Q.A. Coordinator assigned to the Director is make a list using enclosure (3) of all the problems referred to the Director by his Department Heads. The list will be reviewed by the Director weekly. All actions taken by the Director must be documented and a copy given to the referring department. Problems that cannot be corrected by the Director will be forwarded to the Quality Assurance Office for investigation

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28 October 1982

Subj: Quality Assurance/Risk Management Program

and possible action or referral to the Q.A./R.M. Committee.

3. The Quality Assurance/Risk Management Office will review all problems submitted and will investigate those problems that are being reviewed by the Q.A./R.M. Committee. Those problems that can be handled and corrected by the Q.A./R.M. staff using the authority granted to it by the Command will document steps taken to correct the problem. This documentation will be reviewed by the Q.A./R.M. Committee at its next scheduled meeting. Problems not corrected by the Q.A./R.M. staff will be put on the Q.A./R.M. Committee agenda. The Committee will take an aggressive problem solving approach and all actions will be documented. Results of the Committee will be forwarded to the Commanding Officer. All problems not resolved by the Committee will be forwarded to the Commanding Officer with all documentation.

4. The Commanding Officer is the final step in the Q.A./R.M. process. Actions taken at this level are final.



J. J. QUINN

Dist: II

FORMAT FOR DEPARTMENTAL MINUTES

From: Head, _____ Department
To: Commanding Officer
Via: Director, _____ Services
Subj: _____ Departmental Minutes for _____ (month, year)
Ref: (As necessary)

Encl: (As necessary) Branch reports would be listed here.

1. (Paragraph number 1 should describe the nature of the meeting (i.e., monthly, weekly with monthly summarization, etc.), the date and time of the meeting and list attendees and absentees. If preferred, attendance/absence may be listed on an enclosure).

2. Old Business.

a. This paragraph should discuss all items of business which were not completed at the last meeting and are pending. This includes problems which have been solved and currently are due for reevaluation as scheduled on the Department Problem Summary Sheet. Each item must contain clear statements about CONCLUSION(S), ACTION/COMPLETE and MONITOR(S).

b. Where action is requested of other Departments, the minutes plainly should state the apparent problem and request action by that Department. A copy of the Department minutes should be forwarded to the other with a cover memorandum which states the reason for referral and provides applicable standards or references to these standards and enclosed pertinent data upon which the request is based. The Department receiving such a request must document receipt, assessment and resolution in its minutes and provide the referring Department with a copy of the minutes documenting problem resolution.

c. When all appropriate action has been completed and resolution of the problem is beyond the control of any Department, the problem should be referred to the Director of that Department.

Subj: _____ Departmental Minutes for _____ (month, year)

3. New Business.

This section is for documentation of discussion of new items of interest and problems discovered since the previous meeting. Each item must contain clear statements about CONCLUSION(S), ACTION/COMPLETE and MONITOR(S).

4. Morbidity and Mortality.

This area should be included in each monthly minutes. Statistical summaries may be added as appendices; subjects discussed will include case reviews, missed diagnoses, medication errors, etc. Each case or discussion item must contain clear statements about CONCLUSION(S) and ACTION(S).

Care must be exercised to protect the privacy of patients and staff and interests of the Naval Hospital. Departmental minutes are not an appropriate forum for indictment of individual or corporate performance. These matters are handled through formal or informal investigations (authorized by the Commanding Officer), the Quality Assurance/Risk Management Committee or staff or the Credentials Committee.

5. Quality Assurance.

This section is used to report Departmental activities in the area of Quality Assurance. Problems affecting any aspect of patient care, appropriateness of admission, diagnostic procedure or treatment and efforts to identify and study patient care for overall improvement of quality are suitable for discussion. Documentation of Departmental activities are problem-focused and deal with the specific steps of:

- a. Problem identification
- b. Problem prioritization
- c. Problem assessment
- d. Problem resolution by solution or other means

Subj: _____ Department Departmental Minutes for _____ (month, year)

8. Problem Summary.

This section should list, in priority order, problems currently pending in the Department. The Problem Summary Sheet, Enclosure (3) will be used and is a required enclosure for Service minutes and is recommended for Branch minutes. Failure to meet "Milestone Date" requirements should be explained in the minutes. An item will remain on the list until the "Current Status" is "complete"; a "complete" itemusually should be assigned a future review date to assure that the problem addressed does not recur.

9. The meeting adjourned at _____ (time)

(Signature of Department Head)

NOTED AND REFERRED TO APPROPRIATE
DIRECTORATE.

J. J. QUINN
Commanding Officer

Copy to:
Quality Assurance Office

Submitting Department: _____
Contact Point and Phone No: _____

QA STUDY ABSTRACT

DATE

Problem Statement

History

Study Objectives

Sample

Group(s)

Size

Criteria

Methods of Data Collection, Summary and Reporting

Date Start

PREPARING LOCATION: _____

DATE PREPARED: _____

QUALITY ASSURANCE PROBLEM STATUS RECORD

STAKE PROBLEM AND DATE PROBLEM IDENTIFIED	RESPONSIBLE SERVICE/ COMMITTEE/ GROUP/ INDIVIDUAL	NAME OF CONTACT	STAGE OF COMPLETION	COMMITMENTS	
				TARGET DATE TO REVIEW PROBLEM STATUS	DATE PROBLEM SOLVED

QUALITY ASSURANCE/RISK MANAGEMENT PROGRAM
PROBLEM IDENTIFICATION SHEET
NHBETH (01A) (REV. 10/82)

SUBMITTING LOCATION OR DEPARTMENT: _____

DATE SUBMITTED: _____ CONTACT PERSON & PHONE NUMBER: _____

1) PROBLEM IDENTIFICATION:

2) ACTIONS AND OR RECOMMENDATIONS:

3) FOLLOW-UP:

4) SUBMITTED TO THE QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE OR OFFICE:

5) APPROVED BY THE QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE OR RECOMMENDATIONS
MADE BY THE Q.A. COMMITTEE OR STAFF:

6) COMMANDING OFFICERS REMARKS:

APPENDIX F

**NHBETH INSTRUCTION 6320.14 A
Quality Assurance/Risk Management
Program
1 June 1983**



DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
NAVAL MEDICAL COMMAND, NATIONAL CAPITAL REGION

BETHESDA, MARYLAND 20814

IN REPLY REFER TO

NRBETHINST 6320.14A

NRBETH:01:JFP:ph

1 JUNE 1983.

NRBETH INSTRUCTION 6320.14A

From: Commanding Officer

SuJj: Quality Assurance/Risk Management Program

Ref: (a) Accreditation Manual for Hospitals, JCAH
(b) NMCINST 6320.62 (under revision)

Encl: (1) Format for Departmental Minutes
(2) Quality Assurance Problem Status Record
(3) Quality Study Abstract
(4) Quality Assurance/Risk Management Program Problem Identification Sheet
(5) Incident Report/Medical Facility Report
(6) Incident Report Follow up Sheet
(7) JCAH Manual (83 AMH)
(8) NMCINST 6320.62 (under revision)

1. Purpose: This program is designed to enhance patient care through the ongoing assessment of important aspects of patient care and the correction of our identified problems as identified and explained in references (a) and (b). The main objective of this program is to monitor, coordinate, integrate and establish accountability for quality assurance and risk management. All departments (Clinical, Administrative, and Support), all medical disciplines and all staff members and health care practitioners, military and civilian, are required to participate.

2. Cancellation: NRBETHINST 6320.14 and 6320.31A are hereby cancelled.

3. Policy: Each section, branch, department and Director shall demonstrate a consistent endeavor to deliver health care that is optimal, within available resources, and consistent with the mission of the Command and Naval Medical Command Policy.

4. Definitions: The Quality Assurance/Risk Management Program is the plan for assuring the provisions of quality health care, in minimizing monetary loss and providing legal documentation of possible incidents and events. The Quality Assurance/Risk Management Program (henceforth referred to as the QA Program) should be:

a. Comprehensive.

b. Flexible enough to permit innovation and variation in the approaches which are used to:

(1) Evaluate, in diverse instances, whether the "optimal attainable outcome" of health care has been realized.

(2) Identify problems which result in failure to attain this result.

(3) Hasten and facilitate problem solution.

c. Physician supervised.

5. Scope.

a. All health care personnel have a direct or indirect impact upon the quality of health care rendered to patients. It is incumbent upon all to assist in the identification of health care related problems and in effecting solutions to these problems.

b. The Heads of Departments are responsible for the continued identification and resolution (where practical) of problems affecting the quality of patient care within their areas of supervision and to continually monitor the results of these efforts. All problems identified that are outside their areas of supervision and responsibility will be referred to the Director of the Service they come under for further investigation and corrective action.

c. Problems identified and addressed by Special Care Units within the hospital are reviewed by the appropriate Medical Officer supervising these units. These Special Care Units are tasked with meeting the same reporting criteria as any other department in the facility.

d. All problems identified, no matter how small, must be documented. As will be explained further into this instruction, all areas of this facility no matter how small must provide the command with a written monthly report of activities as demonstrated in enclosure (1). Problems identified within sections, clinics and branches must be identified to the department head having control over these areas. This identification will take place either utilizing the incident report or the Quality Assurance/Risk Management Program problem identification sheet problem. Further in this instruction the use of the incident report will be explained in more detail. Basically, the incident report is to be used for reporting one-time events or happenings. The medical facility incident report form NAVMED 6300/11 has been designed to include necessary information about any type of incident. An incident report form must be completed regardless of how minor the problem or incident appears to be. While the incident report form is used for reporting one-time incidents, the Quality Assurance/Risk Management Program Problem Identification Sheet (NBBETE 01A 6320/153 REV 12/82) (enclosure (4)) will be used to report continuing problems requiring immediate corrective action. An example of this would be a ward that does not have linen delivered for two or three days straight. Another example of this is continuous missing instruments from surgical packs or Public Works problems, facility type, that are not corrected within a reasonable time period that affect the operation of the department or area. Neither the incident report nor the Quality Assurance/Risk Management Program identification sheet will be submitted with the monthly minutes. These reports must be submitted separately to the department's directorate and then to the Command Quality Assurance Office.

e. Identified problems which cannot be resolved at the department head level will be referred to the director's administrative assistant or QA Coordinator. The administrative assistant or QA Coordinator will inform their director of the problems referred to them and request assistance from that director in trying to complete or correct the problems identified from their respective departments. Problems that are unable to be corrected on the director level will be itemized by priority and submitted to the Command Quality Assurance Officer by the tenth working day of each month.

f. The Command Quality Assurance Officer will then review the problem as submitted to him or her. The Command Quality Officer will maintain a continuous ongoing listing of problems under each directorate. This master listing will be maintained by calendar year and will show problems that are active and problems that have been completed. Any completed problems that are identified on the list submitted to the Command Quality Assurance Office must have substantiating documentation as to their completion.

g. The Command Quality Assurance Officer will present to the Hospital Executive Committee which serves in the function of the Quality Assurance Committee a listing of problems that have not been completed. This will be done at the monthly Executive Committee meeting. Problems that are referred to the Executive Committee will then be acted upon by the five directors with the Executive Officer being responsible for insuring that action is taken on these problems.

h. All problems referred to the Executive Committee, whether solved or unsolved, will be forwarded to the Commanding Officer for review or further action.

i. Evaluation and review should be problem-focused (i.e., should identify problems, should be effective in resolving problems, and should not merely be intended to document how well care is delivered).

j. As mentioned before, documentation is mandatory in Quality Assurance. This documentation will be accomplished using the forms approved by the Command and JCAH. Enclosure (1) is the only approved format for department minutes. Departments and directorates not adhering to this format will have their minutes returned for corrective and written report forwarded to the Commanding Officer. The example provided by enclosure (1) provides guidelines which will be followed by all submitting departments and all topics listed will be addressed. Other enclosures listed in enclosure (1) will be used. Enclosure (3) QA study abstract, will be submitted to the Command QA office any time a QA study is completed. A QA study is required to be submitted by every department at least once a quarter. This form provides documentation of these required studies (e.g., radiology monthly retake rates, patient waiting times, medication studies, nursing service studies, disaster drills.). Enclosure (2) will be submitted with all monthly minutes even if there are no problems identified in the monthly meeting. No changes are permitted in the format of these forms without prior approval of either the QA officer or the Executive or Commanding Officers.

6. Problem Focused: The Quality Assurance Program is intended to be dynamic, identifying problems upon which to focus corrective action, and ensuring the delivery of high quality health care. There is no single best method for problem identification. When guidelines are used against which to evaluate the quality of health care they will be defined in writing and approved by the involved department, the department heads and the Quality Assurance Officer. If the Quality Assurance Officer questions any of the guidelines submitted, he will forward them to the full Executive Committee for approval. All guidelines will be reviewed annually. Having been identified, a problem will have a priority assigned to it on all levels and action taken to resolve it. Some problems will prove incapable of being resolved with available resources. These problems will have corrective actions applied and then will be periodically reviewed to assure that they remain active until resolved. A monitor will be assigned by name to these problems. All identified problems and all corrective actions taken will be documented in the appropriate minutes. Documentation will be such that one can clearly trace the method of problem identification. This includes the identified problem, the corrective actions undertaken and the followup results of those actions through a sequential review of the minutes.

Enclosure (4), Problem Identification Sheet, will be used to document problems within the department and also will be forwarded to the Quality Assurance Officer. Should a decision be made for any reason not to correct an identified problem, the rationale for such a decision will be clearly documented both in the monthly minutes and in a written statement signed by the department head and submitted to the Quality Assurance Officer.

7. Responsibility.

a. Commanding Officer. The Commanding Officer has the authority to approve or disapprove any decision or recommendation relating to the health care provided at this facility.

b. The Directors. The Directors of Ancillary, Administrative, Nursing, Medicine and Surgical Services will provide support for the program by ensuring staff compliance with the goals and objectives of the Quality Assurance Program. The directors will ensure that all problems identified by them are recorded using the formats given in enclosures (1) through (4) and that no problem is inadvertently dropped short of being resolved. The directors will ensure that any corrective action that can be taken at the directorate level is initiated. Each director will be assisted in the performance of their Quality Assurance functions by both their administrative assistants or Quality Assurance Coordinator. The administrative Quality Assurance assistants to the directors shall prioritize problems identified using a numerical system starting with one (1) which will be the most urgent problem and numbering down. The priority assigned will remain with that specific problem until it is completed.

c. Heads of Clinical and Administrative Departments. Each department head shall establish and maintain a Quality Assurance protocol which shall be submitted to the Quality Assurance office for review and approval. Assessment of care, as determined by the protocol, and documented in the monthly minutes shall be reported to the appropriate director with one copy to the Quality Assurance office and shall include identified problems as well as corrective actions and their results. If the problem cannot be resolved within the service involved, it shall be highlighted in yellow and referred to the administrative assistant of that area's director. The department head will only use reporting format used in enclosure (1) to document the monthly staff meeting.

d. Command Quality Assurance Office. The military staff for the Quality Assurance Risk Management office are special assistants of the Commanding Officer and report directly to him in all Quality Assurance/Risk Management matters. The Commanding Officer and the Executive Officer will serve as physician advisors and counselors to the Command Quality Assurance Program and will further be the physician supervisors of the Quality Assurance Office. The staff of the Quality Assurance Office will serve as advisors to the directors, and the department heads, and is advisor to and investigators for the Executive Committee of the hospital and the Executive and Commanding Officers. Only with the approval of the Commanding Officer or Executive Officer will a Quality Assurance staff investigate problems on the department or directorate level. This office will be tasked with insuring all Navy Department, Naval Medical Command, Naval Hospital, and JCAH quality assurance standards are being adhered to. The Quality Assurance staff will also oversee the JCAH accreditation process. The staff of this office will have full access to all minutes, reports, command files and meetings of the Naval Hospital and will have full access to all hospital spaces. Since Quality Assurance impacts on all phases of health care delivery - the Quality Assurance staff will be an integral part in planning and testing procedures at the Naval Hospital.

The Quality Assurance staff will also be notified in the event of any major emergency so that adequate documentation might be started at the soonest possible moment for possible risk management cases.

c. Quality Assurance/Risk Management Officer. The incumbent will coordinate all Quality Assurance and Risk Management assignments as far as education, training, investigations, and actions required by the Executive Committee or the Command. The Quality Assurance Officer will establish and maintain a Quality Assurance Risk Management training program for the entire staff. The Quality Assurance Officer is further tasked with establishing and maintaining a training program for MSC officers and senior enlisted members of the Hospital Corps in accreditation standards and JCAH procedures. The Quality Assurance Officer, with the authority delegated to him or her by the Commanding Officer, is responsible for overseeing the entire Quality Assurance/Risk Management Program at the Command.

8. Executive Committee/Quality Assurance Committee. The Executive Committee when acting in the mode of Quality Assurance shall initiate Quality Assurance/Risk Management investigations where necessary; and shall act upon problems referred from either the Commanding Officer or the Quality Assurance Officer. The Executive Committee in the mode of the Quality Assurance Committee will provide the Executive and Commanding Officers with monthly reports. The Committee shall meet monthly and will act upon all problems submitted to it. Any problems that cannot be corrected by the Committee will be referred to the Commanding Officer with documentation stating why the problem cannot be corrected on lower levels.

9. Committees Reporting to the Quality Assurance/Risk Management/Executive Committees. The Credentials Committee shall obtain pertinent information regarding each health care practitioner excepting nurses and speech pathologists from the Quality Assurance/Risk Management officer prior to making a recommendation for annual re-certification of the practitioner. The Credentials Committee will provide the Executive Committee/Quality Assurance Committee with copies of all decisions reached and monthly report of any pending action.

10. The Quality Assurance Flow Cycle. The following is how a problem, once identified, is put into the Quality Assurance tracking system. The problem will be documented through the entire process. Copies of documentation must be provided to the area identifying the problem from all levels of the Quality Assurance ladder.

a. Quality Assurance problems will be identified by members of the staff and users. Most problems will originate at the departmental level. Documentation must begin at this level using the format demonstrated in enclosure (1). Problems identified at the department level will be noted in the monthly staff meeting report with status, action and monitor being noted. Problems will then be listed in enclosure (2) and included with the monthly minutes. The monthly minutes (original & copy) with the problem status record attached will then be submitted to that department head's director by the 10th day of the month. Monthly minutes will not be submitted directly to the Commanding Officer's Suite or the Quality Assurance Office.

b. The directors will then review the submitted monthly reports and will attempt to correct problems referred by the department heads. This action is probably the most important in correcting problems in a speedy manner. Communication between the directors will usually get most problems corrected. The Administrative assistants assigned to the director will make a list using enclosure (2) of all the problems referred at the director by his department heads. The list will be reviewed to the director weekly. All actions taken by the director must be documented and a copy given to the referring department. Problems that cannot be corrected by the

director will be forwarded to the Quality Assurance Office for investigation and possible action or referral to the Quality Assurance/Executive Committee. Directors will submit all monthly minutes and copies to the Command QA office by the 20th day of the month.

c. All monthly and quarterly committee minutes (original and 1 copy) will be submitted to the Command QA office when completed.

d. The Quality Assurance/Risk Management Office will review all problems submitted and will investigate those problems that are being reviewed by the Executive Committee. Those problems that can be handled and corrected by the Quality Assurance staff using the authority granted to it by the command will document steps taken to correct the problem. This documentation will be reviewed by the Quality Assurance Committee/Executive Committee at its next schedule meeting. Problems not corrected by the Quality Assurance/Risk Management staff will be put on the Quality Assurance/Executive Committee agenda. The Committee will take an aggressive problem-solving approach and all actions will be documented. Results of the QA/Executive Committee will be forwarded to the Commanding Officer. All problems not resolved by the Committee will be forwarded to the Commanding Officer with all pertinent documentation. The Commanding Officer will review the departmental/committee minutes provided by the Command QA Office. Signature of the Commanding Officer on the minutes and expressed approval or any recommendations, corrective actions or solutions to the problems noted in the minutes. Non-approved departmental/committee minutes will be sent back to the Command QA Office for further investigation and re-submitted.

e. The Administrative Assistant, Director of Hospital Administration will inform all the administrative assistants of the five directors when the departmental minutes have been signed by the Commanding Officer. Each directorate is tasked with obtaining a copy of the approved departmental minutes from the command file. In addition, the Administrative Assistant, Director of Hospital Administration, will inform heads of each committee regarding the status of approval on their committee minutes. Heads of respective committees will be responsible for obtaining a copy of the approved committee minutes.

f. The Commanding Officer is the final step in the Quality Assurance process. Actions taken at this level are final.

11. All physicians, nurses, MSC's and Senior Enlisted staff are required to be familiar with the contents of references (a) and (b). These references shall be maintained in all departments and branches and updated as required.

RISK MANAGEMENT PROGRAM

Definition: The Risk Management Program is the process of increasing the quality of health care by identifying, evaluating, reducing and/or preventing risk or potential adverse events to patients, staff and visitors.

Purpose: To increase the quality of patient care and minimize financial loss to the Navy through integrated system of risk detection, risk evaluation and risk prevention.

Focus: Primary emphasis of this program is to prevent harm by identifying the underlying problem that lead to adverse events and implementing policies, procedures, instructions and training of health care providers to avoid occurrences of adverse events.

Objectives:

- a. To provide an organized reporting mechanism to the Commanding Officer regarding incidents, equipment malfunction, patient dissatisfaction, potential liability claims or unusual circumstances that are not consistent with the routine operation of the hospital or clinic.
- b. To provide for an early detection system through the analysis of data by identifying problem areas before compensable events occur.
- c. To minimize potential liability once an adverse event has occurred.
- d. To provide a cross-reference for liability control that integrates with the quality assurance/risk management problem solving approach within the command.
- e. To reduce potential or actual liability claims through the reduction of incidents.

Elements of Risk Management Program

- a. Risk detection- (problem identification)
- b. Risk evaluation- (problem assessment)
- c. Risk prevention (problem solution)

Risk Detection:

a. Risk detection is the collection and analysis of data to facilitate identification of problems or risks. The quality assurance/risk management officer is responsible for the data gathering function that serves two purposes:

(1) it centralizes risk information and provides the basis for a complete accurate file for legal purposes in the event the medical facility must defend its care, and
(2) it provides for periodic analysis to identify the medical facility's high-risk areas.

Incident Reporting Systems will utilize as the primary source of data for risk detection. Incident Reporting System will be used by all health care providers and staff in identifying potential risk cases.

1. Medical Facility Incident Report Form (NAVMED 6300/11)-(enclosure 5)

The medical facility incident report form NAVMED 6300/11 (enclosure 5), has been designed to include necessary information about any type of incident. The following factors must be considered when submitting an Incident Report into the system:

- a. The individual initiating the incident report must record factual, specific and complete information, and must refrain from extraneous comments based on personal opinion, conjecture or editorial comment.
- b. An incident report form must be completed regardless of how minor the problem or incident appears to be.

c. The incident report form is a working document for the hospital, and must not become a part of the patient treatment record or department minutes..

d. When a patient incident occurs, the medical record should simply document what occurred. It should factually state, in the record what action was taken for the patient. It will not state that an "incident" or "accident" occurred. It will not state that an incident report form was filed, or that the quality assurance risk management coordinator, or other like individual, was notified.

e. Confidentiality must be maintained at all times. NO COPIES OF NAVMED 6300/11 WILL BE MADE. The reports shall be maintained in a secured file and in an area of limited access by command QA office only.

f. In order to maintain the free flow of information, there must be reassurances that the incident report form and the information on it cannot be used against an individual for the basis of disciplinary action. A separate legal investigation must be used for that purpose.

g. The incident report must be completed immediately upon occurrence of an accident or incident. Incident reporting loses its effectiveness if it is delayed.

h. Whenever an incident is reported, additional documentation or follow-up action may be required. Enclosure (6) will be used to provide this documentation. This follow-up form should be started by the Quality Assurance Office if it is felt that additional documentation is required.

i. The incident report form will be used for documentation of accidents or incidents involving patient, visitor, staff or private contractor personnel within the hospitals area of responsibility.

2. Incident Follow-up Report Form

The incident follow-up report form is a supplemental form to be used by the quality assurance/risk management office or the commanding officer's appointed investigator if an incident requires additional documentation and investigation. In completing the form the investigator will record dates and factual information in chronological order. Upon completion of the incident follow-up report form, it must be attached to the original incident report form and retained in the confidential file of the quality assurance/risk management office. This form shall not be used alone but in addition to the incident report form.

3. Incident Report Routing

The following routing steps will be followed by all members of the hospital staff and no exceptions are permitted.

a. PROTOCOL FOR ALL DIRECTORATES EXCEPT NURSING

1) All incident reports generated will be submitted to the head of the department after an occurrence of an incident.

2) After the input by the department head, incident reports must be submitted to the department head's directorate for action (if necessary).

3) Administrative Assistants for each Directorate will submit incident reports to the Command QA Office for additional input.

4) The completed incident with any additional documentation/corrective actions will be submitted to the Commanding Officer within 24 hours of the incident.

5) All incidents involving patient care must contain physician's input and assessment of the incident.

6) Any incidents occurring after hours or on weekends must be reported on an Incident Report and submitted immediately to the ADO.

b. PROTOCOL FOR INCIDENTS OCCURRING ON A NURSING WARD

c. The following steps shall be followed by all members of Nursing Staff when an incident occurs on a nursing ward:

1) Any nursing personnel involved with incident, shall generate an incident report.

2) Ward Medical Officers or Physicians examining patient will report his findings on the reverse of incident reports. If the physician does not see the patient, or sign the incident report within 2 hours of incident, the nurse corps officer will note this in RED ink and forward it.

3) The incident report shall then be hand carried to the Patient Care Coordinator who will in turn, hand carry it to Director of Nursing Service via the Nursing QA Coordinator.

4) The Nursing QA coordinator will forward the report to the Command QA office with any additional report and within 24 hours of receipt.

5) The QA will log the report in and forward it to the Director of Service the patient belongs to, who will report his/her findings back to the Command QA office. The report will be brought to the Commanding Officer by the Command QA officer.

d. After hours, nights and Holidays the following steps shall be taken:

1) Any nursing personnel involved with incidents shall generate an incident report.

2) Ward Medical Officer or attending physician examining patient will report his/her findings on the reverse of report. (If physician does not see or sign incident report within 2 hours of incident, the Nurse Corps Officer will note this in RED ink and forward it to the Nursing Supervisor, who will forward incident report to the Commanding Officer.

3) All incidents will be kept by the ADO for the Command QA coordinator, to be given to the Director of Nursing Service via Nursing QA coordinator at the beginning of the next working day.

4) The incident report shall then follow the procedures described in the protocol for incidents occurring on a nursing ward.

4. Incident Types: All staff members must report any accident or incident falling within the definition of this instruction. In addition, any unfavorable deviation of expectations involving patient care that may be the result of medical management must be reported. Any incident involving security, safety or welfare and discipline

c. Additional data sources will be used by the QA/RM office to facilitate risk detection. Specific guidance governing routing and protocol will be referenced next to each source.

-Liability Claims	(NMCNCRINST 5830.2A)
-JCAH Surveys, Inspector General, Medical	
-IG Reports, Navy Audit Services Reports	
-Department Morbidity & Mortality Minutes	(NEBETHINST 6320.14A)
-Utilization Review Quality of Care Issues	(NEBETHINST 6320.29)
-Command Committee Minutes	(NEBETHINST 6320.28)
-Medical Records	(NEBETHINST 6320.29)
-Patient Contact Program	(NEBETHINST 6320.28)
-Patient Satisfaction Survey	(NMCINST 6320.62 (R))
-Problem Identification Sheet	(NEBETHINST 6320.14A)
-Problem Status Record	(NEBETHINST 6320.14A)
-Informal Investigation (JAG)	(JAGMAN, II, VI)
-Internal Review, Report of	(NEBETHINST 7500.1)

Risk Evaluation

a. Risk evaluation is the process of objectively assessing the cause and scope of the problems or risk identified. High risk or problem areas identified through the collection and analysis of data will be assessed to determine the scope of the problem and how the problem is to be resolved. The assessment may be accomplished by the quality assurance/risk management officer or committee, or the quality assurance/risk management committee may refer the problem to a specific individual, group or service for assessment.

Risk Prevention/Resolution

a. Risk prevention is the process of planning and implementing corrective action to resolve identified problems. Risk prevention must focus on preventing future problems and eliminating or reducing risks. All personnel, civilian and military, are responsible for making themselves aware of the content of this instruction and enclosures and giving it their full support.



J. J. QUINN

Distribution

List II

FORMAT FOR DEPARTMENTAL MINUTES

From: Head, _____ Department -

To: Commanding Officer

Via: Director, _____ Services

Subj: _____ Departmental Minutes for _____ (month, year)

Ref: (As necessary)

Enclosure: (As necessary) Branch reports would be listed here.

1. (Paragraph number 1 should describe the nature of the meeting (i.e., monthly, weekly with monthly summarization, etc.), the date and time of the meeting and list attendees and absentees. If preferred, attendance/absence may be listed on an enclosure).

2. Old Business.

a. This paragraph should discuss all items of business which were not completed at the last meeting and are pending. This includes problems which have been solved and currently are due for re-evaluation as scheduled on the Department Problem Summary Sheet. Each item must contain clear statements about CONCLUSION(S), ACTION/COMPLETE and MONITOR(S).

b. Where action is requested of other Departments, the minutes plainly should state the apparent problem and request action by that Department. A copy of the Department minutes should be forwarded to the other with a cover memorandum which states the reason for referral and provides applicable standards or references to these standards and enclosed pertinent data upon which the request is based. The Department receiving such a request must document receipt, assessment and resolution in its minutes and provide the referring Department with a copy of the minutes documenting problem resolution.

c. When all appropriate action has been completed and resolution of the problem is beyond the control of any Department, the problem should be referred to the Director of that Department and then to the Command Q.A. Office for further action.

Subj: _____ Departmental Minutes for _____ (month, year)

3. New Business.

This section is for documentation of discussion of new items of interest and problems discovered since the previous meeting. Each item must contain clear statements about CONCLUSION(S), ACTION/COMPLETE and MONITOR(S).

4. Morbidity and Mortality.

This area should be included in each monthly minutes. Statistical summaries may be added as appendices; subjects discussed will include case reviews, missed diagnoses, medication errors, etc. Each case or discussion item must contain clear statements about CONCLUSION(S) and ACTION(S). Care must be exercised to protect the privacy of patients and staff and interests of the Naval Hospital. Departmental minutes are not an appropriate forum for indictment of individual or corporate performance. These matters are handled through formal or informal investigations (authorized by the Commanding Officer), the Quality Assurance/Risk Management Committee or staff or the Credentials Committee.

5. Quality Assurance.

This section is used to report Departmental activities in the area of Quality Assurance. Problems affecting any aspect of patient care, appropriateness of admission, diagnostic procedure or treatment and efforts to identify and study patient care for overall improvement of quality are suitable for discussion. Documentation of Departmental activities are problem-focused and deal with the specific steps of:

- a. Problem identification
- b. Problem prioritization
- c. Problem assessment
- d. Problem resolution by solution or other means

Subj: _____ Department Departmental Minutes for _____ (month, year)

This documentation further should indicate that the Quality Assurance activities are comprehensive, integrated and continuous in their scope and performance. Summaries of surveys, audits and other studies are included and the study provided as an enclosure. The Quality Assurance Agenda is a required enclosure to the April minutes. This should present the future Service plan for 2 years of Quality Assurance/Risk Management studies. Goals which are established should be met or the failure to meet them explained. Agenda items should include studies or actions required for accreditation purposes (e.g., monthly or quarterly studies) and those planned as the result of other problem-finding activities.

6. Continuing Education.

This section must document all educational efforts carried out by the Service. It should document training and education provided to others as well as the intra-Service activities. At least a portion of continuing education or inservice training should be the result of problem identification study and solution under such topics

as Morbidity/Mortality case review or Quality Assurance. This should be documented in the minutes.

7. Service Committee and Branch Reports.

Large Services may find that it is advantageous and efficient to conduct any or all of the above activities on the level of Branches. If this is so, Branch and Committee minutes should be summarized in this section of the Service Minutes. Important items requiring further action should be noted as discussed below.

Subj: _____ Service Departmental Minutes for _____ (month, year)

8. Problem Summary.

This section should list, in priority order, problems currently pending in the Service. The Problem Summary Sheet will be used and is a required enclosure for Service minutes and is recommended for Branch minutes. Failure to meet "Milestone Date" requirements should be explained in the minutes. An item will remain on the list until the "Current Status" is "complete"; a "complete" item usually should be assigned a future review date to assure that the problem addressed does not recur.

9. The meeting adjourned at _____ (time).

(Signature of Chief of Service)

Copy to:

Quality Assurance Coordinator

NOTED AND REFERRED TO APPROPRIATE
DIRECTORATE

J. J. QUINN
Commanding Officer

PARKING LOCATION:

QUINN ASSURANCE PROMISE STATUS RECORD

WILHELM (01A) 6320/154 (Rev 11/61)

**RESPONSIBILITY
SERVICES
COMMUNITIES
COURT
INDIVIDUAL**

GRADUATION CEREMONY
NEW YORK

		100
COMMUNI CATION		
DATE PROBLEM SOLVED		
TARGET DATE TO REVIEW PROBLEM STATUS		
STAGE OF COMMUNI CATION		
NAME OF CONTACT		
RESPONSIBILITY SERVICES COMMUNITY GROUP/ INDIVIDUAL		
STAKEHOLDERS AND DATE OF INITIATION/TRANSITION		

QA STUDY ABSTRACT

DATE

Problem Statement

History

Study Objectives

Sample

Group(s)

Size

Criteria

Methods of Data Collection, Summary and Reporting

Date Start

101

Date Complete

QUALITY ASSURANCE/RISK MANAGEMENT PROGRAM

PROBLEM IDENTIFICATION SHEET

NUBETH (Q.A.) 6120/153 (Rev. 12/82)

SUBMITTER, LOCATION OR DEPARTMENT:

DATE SUBMITTED:

CONTACT PERSON & PHONE NUMBER:

1) PROBLEM IDENTIFICATION:

2) ACTIONS AND OR RECOMMENDATIONS:

3) FOLLOW-UP:

4) SUBMITTED TO THE QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE OR OFFICE:

5) APPROVED BY THE QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE OR RECOMMENDATIONS
MADE BY THE Q.A. COMMITTEE OR STAFF:

6) COMMANDING OFFICER'S REMARKS:

MEDICAL OFFICER EXAMINING PATIENT	Nature of Injury - Findings - Treatment	Extent of Injury	<input checked="" type="checkbox"/> None <input type="checkbox"/> Serious	<input type="checkbox"/> Minor <input checked="" type="checkbox"/> Severe
Name of Examining Physician (PRINT)	Signature/GRADE	Work Telephone No.	Date	Time
WITNESS OBSERVING INCIDENT	Name	Telephone No.		
	Home Address	City/State/Zip		
	Name	Telephone No.		
	Home Address	City/State/Zip		
Incident Report Routing Comments:				
QUALITY ASSURANCE/ RISK MANAGEMENT COORDINATOR OR DESIGNATED INDIVIDUAL INVESTIGATING AND EVALUATING THIS INCIDENT	Problem Identified:			
Name of QA/RM Coordinator or Investigator (PRINT)	Signature/GRADE	Date		

* Notify and forward Incident Report form to Quality Assurance/Risk Management Coordinator, or follow routing procedure determined by Commanding Officer/Officer in Charge

INCIDENT REPORT NUMBER: _____

This form is only used by the Command Quality Control Office.

INCIDENT FOLLOWUP

1. BRIEF DESCRIPTION OF INCIDENT (INCLUDE DATES)

2. SUMMARY FROM PROGRESS NOTES, NURSING NOTES, AND OTHER CLINICAL RECORDS (HOSPITAL, OUTPATIENT, LAB, X-RAY RESULTS, ETC.) - INCLUDE DATES AND SOURCE

3. PATIENT COUNSELLING

4. STAFF COUNSELLING

5. RECOMMENDED ACTION

6. ADDITIONAL COMMENTS (IF APPLICABLE)

7. INDIVIDUAL COMPLETING FORM (GRADE/RATE/TITLE)

8. PATIENT'S NAME (LAST, FIRST, M.I.)

9. PATIENT'S SSN

10. DATE OF REPORT

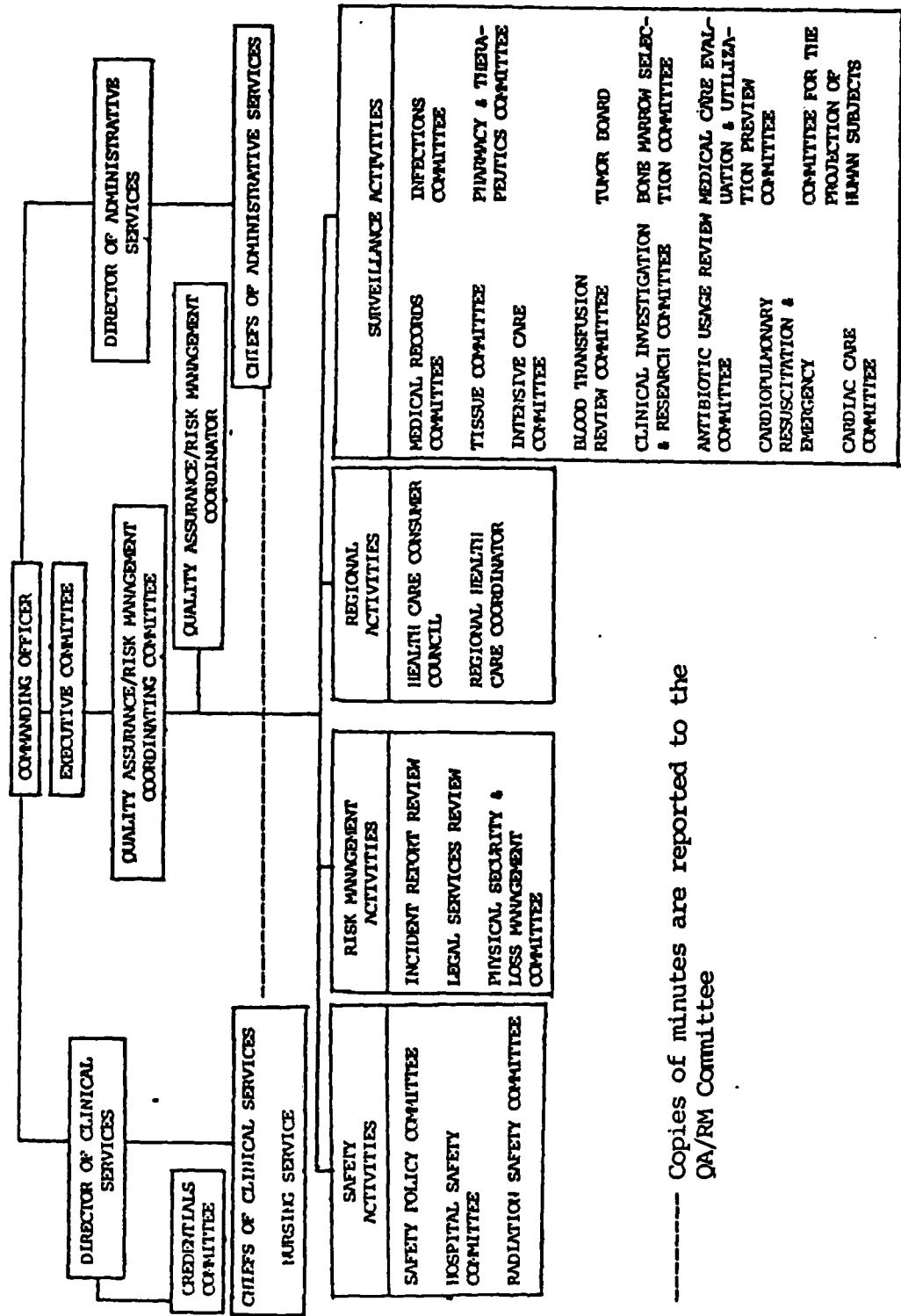
OVER

APPENDIX G

National Naval Medical Center
Quality Assurance/Risk Management
Organizational Chart
2 February 1981

NATIONAL NAVY MEDICAL CENTER, BETHESDA, MARYLAND

QUALITY ASSURANCE/RISK MANAGEMENT ORGANIZATION CHART



----- Copies of minutes are reported to the
QA/RM Committee

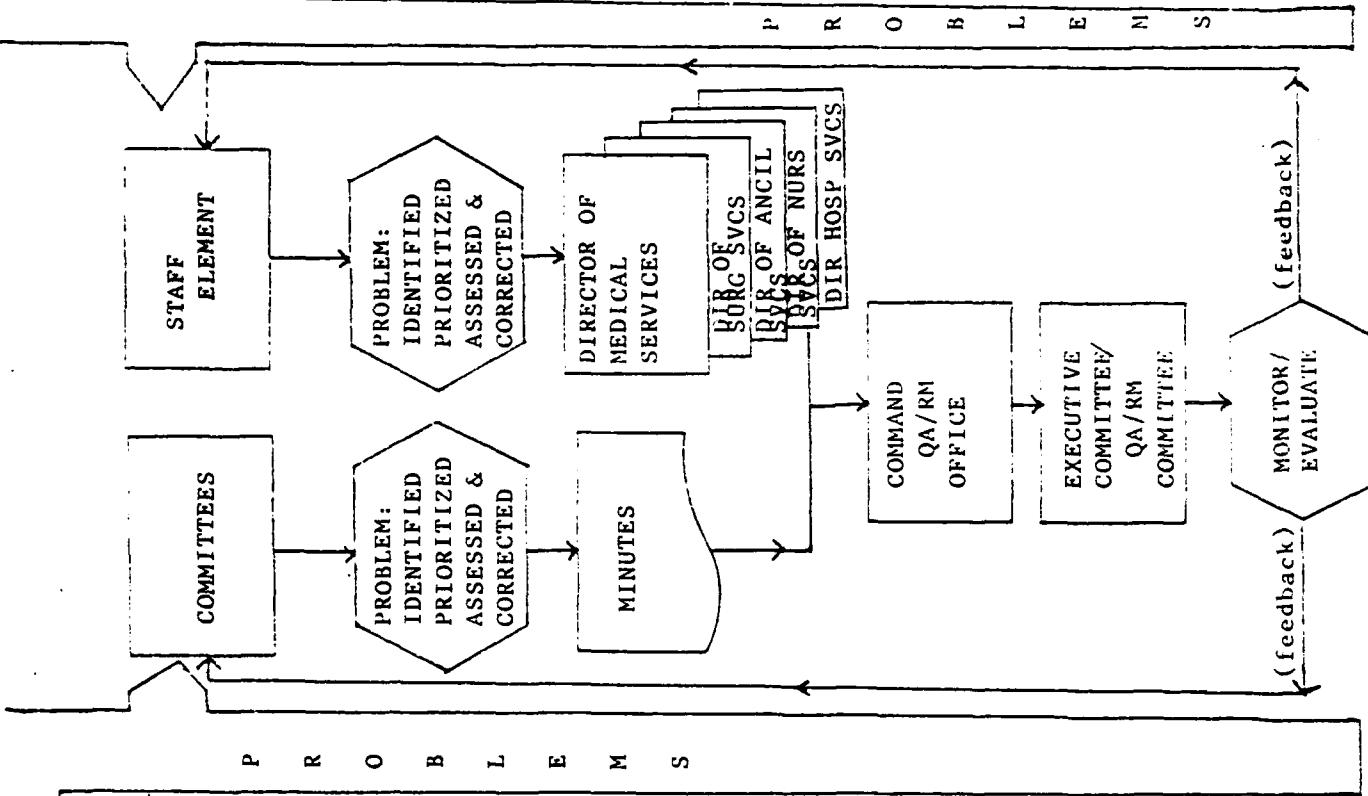
APPENDIX H

**Naval Hospital Bethesda
Quality Assurance Process
28 October 1982**

QUALITY ASSURANCE PROCESS

DATA SOURCES FOR PROBLEM IDENTIFICATION

- 1. EXTERNAL SOURCES:**
- Instructions and directives from BUNED
 - Inspector General Inspections
 - Manpower surveys
 - Joint Commission on Accreditation of Hospitals
 - Accreditation surveys:
 - JCAH
 - College of American Pathologists
 - American College of Surgeons
 - AMA
 - Other inspections/surveys:
 - Federal Drug Administration
 - Nuclear Regulatory Commission
 - NOSHIPS
 - Patient complaints:
 - Surgeon General
 - Patient Contact Representative
 - Congressional inquiries
 - Literature related to health care



- 2. INTERNAL SOURCES:**
- Statistical reports:
 - Comptroller
 - Patient Affairs
 - Unusual Occurrence Reports
 - Patient Surveys:
 - Satisfaction
 - Clinical waiting time
 - Infection Control Surveys
 - Medical/Patient Care Audits
 - Staff Interviews
 - Blood Utilization Reports
 - Laboratory reports
 - Pharmacy reports
 - Committee reports
 - Service reports
 - Management surveys
 - Staff report
 - Medical records
 - Utilization Review reports
 - Review of known or suspected problem areas
 - Liability claims (JAC)
 - Manual investigations
 - Consumer Council meetings
 - Patient Contact
 - Representative data

APPENDIX I

**Quality Assurance/Risk Management Program
Problem Identification Sheet
NHBETH (OIA)**

QUALITY ASSURANCE/RISK MANAGEMENT PROGRAM
PROBLEM IDENTIFICATION SHEET
NHBETH (01A) (REV. 10/82)

SUBMITTING LOCATION OR DEPARTMENT: _____

DATE SUBMITTED: _____ CONTACT PERSON & PHONE NUMBER: _____

1) PROBLEM IDENTIFICATION:

2) ACTIONS AND OR RECOMMENDATIONS:

3) FOLLOW-UP:

4) SUBMITTED TO THE QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE OR OFFICE:

5) APPROVED BY THE QUALITY ASSURANCE/RISK MANAGEMENT COMMITTEE OR RECOMMENDATIONS
MADE BY THE Q.A. COMMITTEE OR STAFF:

6) COMMANDING OFFICERS REMARKS:

APPENDIX J

**Quality Assurance Problem Status Record
(PSR)**

PREPARING LOCATION: _____

DATE PREPARED: _____

QUALITY ASSURANCE PROBLEM STATUS RECORD

STATE PROBLEM AND DATE PROBLEM IDENTIFIED	RESPONSIBLE SERVICE/ COMMITTEE/ GROUP/ INDIVIDUAL	NAME OF CONTACT	STAGE OF COMPLETION	TARGET DATE TO REVIEW PROBLEM STATUS	DATE PROBLEM SOLVED	COMMENTS

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SELECTED BIBLIOGRAPHY

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